U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

TUESDAY, JANUARY 29, 2013

The Committee convened in Rooms E1/E2, Natcher Conference Center, National Institutes of Health, Bethesda, Maryland, at 10:00 a.m., Dr. Thomas Insel, *Chair*, presiding.

PARTICIPANTS:

THOMAS INSEL, M.D., *Chair*, IACC, National Institute of Mental Health (NIMH)

SUSAN DANIELS, Ph.D., *Executive Secretary*, IACC, National Institute of Mental Health (NIMH)

IDIL ABDULL, Somali American Autism Foundation

JAMES BALL, Ed.D., BCBA-D, JB Autism Consulting and Autism Society

ANSHU BATRA, M.D., Our Special Kids

JAMES BATTEY, M.D., Ph.D., National Institute on Deafness and Other Communication Disorders (NIDCD)

JOSIE BRIGGS, M.D., National Center for Complementary and Alternative Medicine (NCCAM) (representing Francis Collins, M.D., Ph.D.)

NOAH BRITTON, M.A., Bunker Hill Community College

SALLY BURTON-HOYLE, Ed.D., Eastern Michigan University

PARTICIPANTS (continued):

MATTHEW CAREY, Ph.D., Left Brain Right Brain

DENNIS CHOI, M.D., Ph.D., State University of New York at Stony Brook

JOSE CORDERO, M.D., M.P.H., University of Puerto Rico

JAN CRANDY, Nevada State Autism Treatment Assistance Program

GERALDINE DAWSON*, Ph.D., Autism Speaks

DENISE DOUGHERTY, Agency for Healthcare Research and Quality (AHRQ)

TIFFANY FARCHIONE, M.D., U.S. Food and Drug Administration (FDA)

ALAN GUTTMACHER, M.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

LAURA KAVANAGH, M.P.P., Health Resources and Services Administration (HRSA)

DONNA KIMBARK, Ph.D., U.S. Department of Defense (DoD)

WALTER KOROSHETZ, M.D., National Institute of Neurological Disorders and Stroke (NINDS)

CINDY LAWLER, Ph.D., National Institute of Environmental Health Sciences (NIEHS), (representing Linda Birnbaum, Ph.D.)

DAVID MANDELL, Sc.D., University of Pennsylvania

JOHN O’BRIEN, M.A., Centers for Medicare and Medicaid Services (CMS)

PARTICIPANTS (continued):

LYN REDWOOD, R.N., M.S.N., Coalition for SafeMinds

CATHY RICE, Centers for Disease Control and Prevention (CDC)

SCOTT ROBERTSON, M.H.C.I., Autistic Self Advocacy Network

JOHN ROBISON, Self-Advocate

ALISON TEPPER SINGER, M.B.A., Autism Science Foundation

LARRY WEXLER*, Ed.D., U.S. Department of Education (ED) (representing Michael Yudin)

*attended by phone

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PROCEEDINGS:

Dr. Thomas Insel: Good morning, everybody. Let's find our seats. And let me welcome you to the Interagency Autism Coordinating Committee. How wonderful not to have a super storm today, or either a hurricane or a massive snowstorm or something else that would keep us from being able to meet.

Some of us were getting a little superstitious about that, but not reading in any celestial implications, just realizing that sometimes correlation and causation don't match. And we were just unlucky for a couple of meetings, but it's great to have everybody finally here and getting together.

I know some of the Committee were able to get together last evening for a social event, which I think is a great idea, something we want to try to continue in the future.

We may have at least one or two members

who will be joining us on the phone. And of course, there are many members of the public who will be listening in as a conference call or Webcast.

We also have, there's one right there, and there are also several people who are in the room to be able to join us today either for public comment or just as observers. We're delighted to have them.

Could we go around and do a quick roll call and just have people introduce themselves very quickly so those on the phone will know who's here? I'll start. I'm Tom Insel, the Chair of the Committee and Director of NIMH at NIH. Jim?

Dr. James Battey: I'm Jim Battey. I'm the Director of the National Institute on Deafness and Other Communication Disorders.

Dr. Dennis Choi: Dennis Choi from SUNY, Stony Brook.

Mr. John Robison: John Elder Robison.

Dr. Josie Briggs: Dr. Josie Briggs. I'm the Director of the National Center for

Complementary and Alternative Medicine. And I have the honor of representing Dr. Collins on this Committee.

Dr. Matthew Carey: Matt Carey, I'm a parent.

Dr. Jose Cordero: Jose Cordero, University of Puerto Rico.

Dr. Donna Kimbark: Donna Kimbark, the Department of Defense.

Dr. James Ball: Dr. Jim Ball, the President and CEO of JB Autism Consulting.

Dr. Cindy Lawler: Cindy Lawler here today representing Linda Birnbaum from National Institute of Environmental Health Sciences.

Ms. Laura Kavanagh: Laura Kavanagh with the Maternal and Child Health Bureau, Health Resources and Services Administration.

Dr. Tiffany Farchione: Tiffany Farchione with the Division of Psychiatry Products at the Food and Drug Administration.

Mr. Scott Robertson: Scott Michael Robertson, Vice Chair of Development and Co-

Founder of the Autistic Self Advocacy Network.

Ms. Lyn Redwood: I'm Lyn Redwood with the Coalition for SafeMinds. I'm the mother of a 19-year-old boy, and I'm going to use the R word today for recovery.

Ms. Jan Crandy: My name is Jan Crandy and I'm with the Nevada Commission on Autism Spectrum Disorders and I'm also a case manager for the State Autism Treatment Assistance Program, and I'm also a mother of a 19-year-old best-outcome child. Thank you.

Dr. Catherine Rice: Hi, I'm Catherine Rice with the Centers for Disease Control and Prevention representing Dr. Coleen Boyle.

Mr. John O’Brien: I'm John O'Brien with the Centers for Medicare and Medicaid Services.

Ms. Idil Abdull: Hi, I'm Idil Abdull. I'm an autism mom, and I'm also from Somali American Autism Foundation.

Dr. Sally Burton-Hoyle: My name is Sally Burton-Hoyle. I am from Eastern Michigan

University's Autism Collaborative Center.

Ms. Alison Singer: I'm Alison Singer. I'm Co-Founder and President of the Autism Science Foundation, and I'm the mother of a 15-year-old daughter with autism and legal guardian of my 48-year-old brother with autism.

Dr. Walter Koroshetz: Hi, I'm Walter Koroshetz. I'm Deputy Director of the National Institute of Neurological Disorders and Stroke.

Dr. Anshu Batra: Anshu Batra, parent of a 15-year-old son with autism.

Dr. Denise Dougherty: Denise Dougherty, Agency for Healthcare Research and Quality.

Dr. David Mandell: David Mandell, University of Pennsylvania.

Dr. Susan Daniels: Susan Daniels, acting Director of the Office of Autism Research Coordination that helps manage the Committee.

Dr. Insel: And who do we have on the phone? Anyone?

Dr. Larry Wexler: Larry Wexler from

Department of Education. Good morning.

Dr. Insel: Good morning. Anyone else? Geri?

Dr. Geraldine Dawson: Good morning. I'm Geri Dawson, Chief Science Officer for Autism Speaks and Professor of Psychiatry at UNC Chapel Hill.

Dr. Insel: And Alan Guttmacher will be joining us a little bit later in the morning. I think Alice Kau is going to be here as well, sitting in from NICHD.

We have one new member of the Committee. Alexa Posny has left the Department of Education. So she's going to be replaced by Michael Yudin, who is the acting Assistant Secretary for Special Education and Rehabilitative Services in the Department of Education.

Michael Yudin formerly served as the Principal Deputy Assistant Secretary for the Office of Elementary and Secondary Education. Just a quick rundown on his bio: He helped lead policy development and operations of all grant programs administered by this Office, designed to promote academic excellence and ensure equitable opportunities for educationally disadvantaged students.

Mr. Yudin also helped lead the Department's efforts on Elementary and Secondary Education Act flexibility, and he served as acting Assistant Secretary for Elementary and Secondary Education from June 2011 to May 2012.

So we're delighted to have Michael join the Committee for Alexa. And in the meantime, because he couldn't attend today, as you just heard, Larry Wexler will be sitting in from the Department of Education. Larry, it's good to have you with us on the phone. So don't be shy. Speak up as the occasion arises.

Dr. Wexler: Thank you.

Dr. Insel: We have had a tradition of doing a couple of things at the beginning of each meeting. One is to make sure we review and approve, or review and if necessary, edit the minutes from the previous meeting. So

Susan, do you want to take us through those very quickly?

Dr. Daniels: So I sent it out ahead of time so that the rest of the Committee could look at these minutes. If you have any specific comments, you can mention them here, or email me afterwards to let me know that anything needs to change.

And because this Committee's new, I just reminded you that we do have transcripts and video that are verbatim what was said in the meeting. This is supposed to be a summary that goes over the main topics that were discussed in the meeting.

So were there any concerns regarding these minutes? All in favor of accepting the minutes as written?

(Chorus of ayes.)

Dr. Daniels: Any opposed? Any abstaining? The motion carries to pass the minutes.

Dr. Insel: Great. Thanks, Susan. In addition, in your folders you'll find both written comments and public comments – oral comments from the public that have come in since our last meeting.

So those were sent ahead of time to make sure you had a chance to review them. Also, you'll find some biographies of the people who will be with us today.

We have a fairly full agenda based on recommendations that many of you made, things that you thought we should put on our plate.

I wanted to make sure we reserved sometime this afternoon to have a very frank discussion about where we go from here. What are the things that the IACC wants to accomplish over the next 1 year and 9 months?

I think the clock is ticking, so we don't have a lot of time to waste if we want to have some significant impact. And what we hope to do this afternoon, and what we've called on the minutes as sort of a business session, or IACC business, is to really get from you some thoughts and suggestions for kind of an action plan of what's next.

And I think, or I know many of you already have ideas about that. There have been some conversations. But this needs to be a good discussion amongst all of us to think about where we go from here.

Now that the Strategic Plan update for research is done, it's a good time to step back and ask what are we going to do for the services agenda and for other aspects of what the Committee is chartered to do.

The other tradition we have at the beginning of each meeting, and I'm not even sure how this got started, but for the last several years we've used about 15 minutes at the beginning just to do a quick update on new science findings, any discoveries that have been out in the last few months that we want to make sure you know about to the extent possible that we hope these will help to inform you about how the research community is responding to the Strategic Plan.

And I want to just take you through

those very quickly. This is not in any sense meant to be comprehensive or very detailed.

But it's really an attempt by the OARC folks, as well as your Chair, to try to grasp what are the trends in the science of autism that we think will be helpful for the Committee to know about in planning for either the Strategic Plan or for an update.

So very quickly, and to the extent possible, these are meant to be over the last 2 or 3 months. But sometimes, these clickers, there we go, we've extended a little bit further back.

On question one, when should I be concerned, many of the issues that are now emerging from the literature are quite different than where we were 4 or 5 years ago with an interest in beginning to think about what is changing before the symptoms of autism emerge.

And one of the insights we have from research on Alzheimer's and Parkinson’s and Huntington’s and many other brain disorders is that behavior is the last thing to change – that we see changes in the brain often years – in the case of Alzheimer's, decades – before you see dementia.

And so it's not surprising that people have begun to ask what may be changing, what may be evident in terms of brain activity in the first year for children at very high risk for autism that may emerge even before there are behavioral changes.

And this is an attempt to capture some of that literature suggesting that if one looks at brain responses to eye gaze, brain responses to speech, even in the first year between 6 and 12 months, there are some fairly striking differences in those children who are at high risk, particularly those who will go on at age 3 to have a diagnosis of autism.

In addition, there is the beginning of an attempt to put together genetic findings from some 230 or so genes for a potential diagnostic biomarker.

Not entirely successful, but the group from Australia shown at the bottom here predicting the diagnosis of ASDU with gene pathway analysis is a first attempt to do that mostly as a proof of principle.

How could I understand what is happening? Well, here, I would say that if there's one trend that emerges over the last 6 months, it's an increasing interest in inflammation and immune responses, to some extent growing out of the extraordinary work with mice, in which one can show that by doing an immune challenge during pregnancy, so sort of midway through gestation, the mice that emerge have both immune dysregulation, in terms of peripheral markers, but also some rather striking behavioral changes that in some ways may be relevant to both the social deficits and, as they argue in this paper, the communication deficits in autism.

Maybe more to the point is the first PET study that was published just last month or earlier this month from Japan suggesting that a marker of microglia shows that people, in this case adults, with autism have the same pattern of microglial activation in the brain, but actually more of it in the same areas.

So, an interesting observation that I think is going to need to be replicated. But it goes along with this idea that we've heard about at previous meetings about the importance of inflammation.

And then just out these past few days is a study from the Finnish cohorts looking at, in this case, 1.2 million births in Finland from about a decade or more ago.

And looking at blood samples that were taken kind of at the end of the first trimester, early second trimester measuring C-reactive protein, which is a kind of long-acting inflammatory marker – not specific, but often very helpful for getting a general sense of whether there's inflammation going on.

And what Alan Brown and his colleagues

reported is that if you separate out that huge number of samples and you just kind of cut these into either quartiles, quintiles, or deciles and you compare the highest group and the lowest group, for the top fifth compared to the bottom fifth, there's about a 45-percent increase risk for autism in the top fifth.

And if you actually go to the top tenth, it goes up to about an 80-percent increased risk for autism, suggesting that maybe there is, in many cases, something going on in terms of inflammation here at the end of the first or beginning of the second trimester.

Again, an issue that we've heard about earlier in the course of our conversations in the Committee. And the similar kind of study that was done, in this case, 100,000 children out of Denmark, looking for a history of influenza or other infections or high fevers.

Again, a similar picture begins to emerge that either mostly it looks like mid-second trimester there's about a twofold higher risk for moms who had influenza.

And the authors sort of, in some ways, dismissed this, saying that this emerged from many, many other, in the context of many variables that they looked at.

So they're not sure if this is real or not or whether it's just a function of multiple comparisons. But certainly worth looking at further. And it raises the same kind of question about infection and inflammation in terms of potential causative factors.

There's been an enormous amount of work on genetics. There's no way we can begin to summarize that here, except to point out a pair of papers that came out this past week, I think on Friday in *Neuron,* suggesting, again, that this space for identifying people who have a genetic lesion that has put them at risk, which would have said only 3 or 4 years ago was maybe 8 percent of the autism population is continuing to grow, 16 percent then 20, 25 percent.

And with this new paper from Mark Daly and his colleagues, it extends even further by looking at these what seem to be rare events, rare mutations. And yet when you look at enough people, they begin to add up and to explain a fair amount of the risk.

On another form of cause, we've talked about this a little bit in some of the phone calls we've had in doing the update, the Volk et al. paper that looks at traffic-related air pollution, in this case, again, finding about a twofold higher risk for people exposed to high levels of air pollution during pregnancy, during gestation goes up even a little bit more over the first year postpartum.

So again, another story about environment. And these are just in terms of risk factors at this point, and not causative factors.

Treatments. Again, interesting kind of tale of two cities here. On the one hand, very exciting information about arbaclofen, which is a gaba-B agonist, which has been used for years for spasticity and a whole series of other developmental disorders. now being tried for Fragile X with mixed results. But the part of it that looks most positive has to do with the social deficits or social engagement, which has been encouraging enough for the same group to now launch a study in children with autism. So more on that, I think, as that Phase II trial begins to develop.

And then I wanted to point out, perhaps most importantly, this report from a supplement to *Pediatrics* that came out, I think, in November from a technical expert panel that looked very closely at over 300 papers on behavioral interventions for children with ASD.

So this was not adults. It was looking only at children, and adolescents were included here. Actually, I think, Anshu, you were part of this technical expert panel. So you may be able to tell us more about this.

But this may be something that we should circulate, if you haven't seen it already so that the Committee knows about this because the conclusions were that we just really don't have enough evidence, that there's a very thin evidence base for many of our behavioral interventions.

They gave sort of moderate scores to three or four that we all know well, lower scores to many other kinds of interventions that we talk about here.

And the real concern that best practices of clinical trials, randomization, blinding, careful attention to standardized outcome measures, are really missing from this literature and that we need to take a hard look at where this literature is and to think about next steps.

So I put this up here not so much as a breakthrough, but as a wake-up call for the community. And I think this group did a nice job through the HRSA network in helping us all to think about where the state of the art is.

And maybe we can take a couple of minutes after I'm finished to get some more comments about this from Anshu or others who have been involved with this.

Quickly, on the question specifically of services, and I apologize, I think David Mandell is a co-author on every one of these papers. So David, this was not selected in any way to promote your research career. But it is striking that there's a lot of productivity recently around many of the issues that the IACC has been concerned with.

I won't take you through any of this in detail, especially with David present. But sufficient to say that the first one on comparing outcomes is a really well-designed study that shows the value of inclusive programs as opposed to disability specialized programs.

And David may want to say more about that, but it's pretty striking. The second paper is another one that I think the

Committee needs to chew on because this is something that I hope we can talk about further as the day goes on.

It's comparing health care service use and costs for ASD – essentially doing Medicaid versus private insurance. And if you had to just find the bottom line, it's about a fourfold difference between what people receive under Medicaid versus what they're receiving under private insurance. Is that fair to say?

And this paper breaks this down into much greater detail, suggesting that most of the differential costs have to do with outpatient treatment, and particularly with some of the behavioral interventions.

This requires a lot more discussion from the Committee. And maybe, David, we could get you to weigh in on this later in the day or after this because I think it's really significant.

And finally, I had to put up this last paper because it really comes right out of the IACC's call for looking at the issue of elopement.

This was the IAN, the Interactive Autism Network, survey that was done and finally published in October based on the IACC call for data about elopement and shows that some, almost 50 percent of families, are particularly concerned about this issue.

And in about a quarter of the cases, there is a real risk for danger. So this was important to kind of loop back and let you know that not only did we put together a statement about this that went to the Secretary.

Not only did that lead to coding changes, but it led to a report in *Pediatrics* with data that everybody could see from the survey. So it's a good example of one of the ways that this Committee can have real impact.

A couple of other questions, just to address on what does the future hold. This continues to be an area that I think is most striking for the lack of publications, the lack of productivity in the research community.

There's a little work coming out around the different trajectories and recognizing that we've got a real challenge that, while people seem to be improving in the early stages posttransition, in their late adolescence, early twenties; there's a real plateau effect by late twenties.

And this paper in the *Journal of the American Academy of Child and Adolescent Psychiatry* documents how that plateau happens at around 25 to 30 in almost all cases, irrespective of the setting or of the diagnosis.

And then Jeremy Veenstra-VanderWeele's review, and again, I don't usually put reviews into these descriptions, but this one, I think, is important for IACC to see because in looking at vocational interventions, Jeremy came around to saying there's just no there there.

We really need some decent information about what works and what doesn't. And what we have are mostly anecdotes or small-scale studies that have not been randomized, blinded, and done with any real rigor.

So a call for some much more scientific approach to the question of vocational intervention is an important point for us to hear.

I'll finish with just this one on the infrastructure and surveillance needs. We've talked about other surveillance projects leading up to the update. But since this just came out, I thought you might want to know about an attempt to go back to a study done in the mid-eighties looking at a population-based diagnosis of autism and asking, if we go back to those kids and look at the records and try to understand now, would they still be called autistic? What would we find?

And in that case, what was really valuable in this is that they looked at a huge number of kids in the 1980s, who were deemed not to have autism.

And now looking at changes in diagnostic criteria, this group felt that about 50 percent of those, maybe a little bit more than that, would actually have been called autistic in 2012 when they were not in 1986, I think it was.

So it's simply the point being made that, whatever the change in prevalence rates are, whatever's driving this, at least one of the factors does seem to be change in diagnostic criteria.

I don't think that will be a surprise to anybody in the room. They end up saying we still don't know how much of a driver that is overall.

But they could at least say from the Utah study that there was a fairly significant increase based on just the diagnostic changes.

So that's a real quick rundown. We can take maybe a couple of minutes and see; as I said, this is not going to be comprehensive.

There are lots of papers out even in the last month that I didn't cover.

But I wanted to capture some of the trends. And I think we really are seeing some kind of emerging ideas that were not around a year ago.   Jose?

Dr. Cordero: Thank you for a very, very nice review. I had a little bit of a deja vu with the study on autism and growths and particles because there are two papers also suggesting the same kind of association was prematurity.

And in prematurity, the process of inflammation is actually, it seems to be, the main thrust, especially for late preterms. So it is a very interesting, let's not call it coincidence, but interesting observation to follow up.

Dr. Insel: Yes, great point. And same thing, of course, is true for C-reactive protein, which has also been implicated. So if you pick up a high CRP in the first trimester, second trimester – very high levels of prematurity and birth complications.

David, anything you want to say about the Medicaid numbers, because I was pretty struck by that specific difference?

Dr. Mandell: Sure. So there were two issues there. One is the large volume of community-based services that people can access through Medicaid that they just can't access through private insurance that are probably particularly important when you think about creating an environment, in which people can function optimally in their own communities.

The second had to do with medication. And medication use in Medicaid was a lot more expensive than medication use in private insurance.

I don't think it's because private insurance negotiates better rates than Medicaid does. But it may have something to do with the medication practice and may have something to do with, you know, there's a huge socioeconomic disparity in these two groups.

And so while I think that, you know, so there may be one positive cause, something that's positive for people in Medicaid in that they're receiving better outpatient services.

But I also think that we need to spend a lot of time looking at medication management in Medicaid and make sure that it as optimal as it could be because that may be driving a lot of the difference in expense, as well.

Dr. Insel: And I think that as I read this, the take-home message was that Medicaid is as good as it gets right now. And with John here, I mean, I think it's in a way a very positive statement about what the Federal Government helps to happen.

Dr. Mandell: Yes, you said it very well. There's no question that, if I were advising someone who had a child with autism about how to maximize the health care their child was receiving, I would steer them toward the publicly funded system.

Dr. Insel: Other comments before we move on? Idil?

Ms. Abdull: I was wondering, David, thank you for that, if you could elaborate a little bit about when you say Medicaid, there is the waiver Medicaid, which, even though it's under Medicaid, then there is a racial disparity, right?

And then there is the Medicaid that is public insurance that almost covers way worse than even the private insurance.

So you can get a lot of services if you have the autism Medicaid waiver, but if you have just the straight Medicaid or Medical Assistance, as we call it in Minnesota, it doesn't really cover any of the early behavior interventions; it doesn't really cover, John correct me if I'm wrong, the ABA.

So I wonder if you can talk a little bit about that, because a lot of people might think, well, Medicaid is good, it covers all these things.

But it's if you have the waiver. And not many states have waivers. And then there's the racial disparity, right?

Dr. Mandell: I'll talk about it for a minute because I know I don't want to get us too far off schedule. But, so nine states have autism-specific Medicaid waivers.

Almost every state has a developmental disability waiver that people with autism are often eligible for. Even if you look in those states without autism waivers, people on Medicaid are receiving a lot of Medicaid-reimbursed care relative to what's occurring in private insurance.

We can argue, and I would be on your side in arguing, those services may not be the most appropriate for people with autism.

And we also have done some further research showing that a lot of the benefit of Medicaid is in fact limited to people who are receiving waiver-reimbursed services as opposed to receiving services through the general Medicaid state plan.

I think the larger point that I would agree with Tom on is there's a lot of money being spent on these children through the Medicaid system.

We could probably take that same money and do a lot better job of organizing those services, making decisions about what those services should be, and improving their quality.

But I don't think it's an issue of spending more money on those kids in that system. It's an issue of improving the quality and appropriateness of what they're getting.

Dr. Insel: John?

Mr. O’Brien: David, I'm glad you said that last piece because I think that's one of the things that we're feeling would be very helpful for a number of folks to help us think through.

Number one, most of the terms of what we're spending is part of the waiver, but we're in discussion, and in some cases submissions for states where they're thinking broader than the 1915 (c) waiver.

And so as states come to us with what they want to cover, you know, partially we've got a history of what we've covered, but partially we would like to know, well, what questions should we be asking them about coverage as they begin to have those conversations with us?

I think we would be fascinated at looking at the medication data. It sounds interesting. And perhaps that's a longer online/offline conversation. But let's try to find some time to do that.

Dr. Mandell: We should have lunch sometime.

Dr. Insel: Lyn?

Ms. Redwood: Tom, I just wanted to comment on the study regarding inflammation during the prenatal period. And I specifically have concerns, from looking at the research literature, regarding the recommendation to vaccinate pregnant women, especially during the first and second trimester with the flu vaccine.

We know from previous studies in pregnant women, especially those that had depressive symptoms, that they had an increased immune response.

And we know from the work of Paul Patterson in animal models when he's used the same marker as vaccination in animal models, that it resulted in an immune response in the offspring, as well, that was associated with abnormal brain development and also behavior.

So we really don't have any long-term studies to look at the policy of recommending vaccinations, not only for flu vaccine, but now for pertussis during pregnancy.

And we know that those cause the same type of immune response as the wild infection. So I think that's something that needs to be on our radar screen in the future in terms of looking at these inflammatory responses during pregnancy.

Dr. Insel: Good, thank you. I think,

let's take a last comment from Scott, and then we'll have to move on.

Mr. Robertson: So I just wanted to comment just briefly on what you had mentioned on the adult research areas and lifespan issues.

And it was really striking to me, for instance on the vocational review paper, how we still, you know, many, many years later, people have been commenting how we didn't have really good research in these areas for years.

And it looks like it hasn't changed as significantly as it should have. So I hope that's something that we can have maybe on discussion later on is how we can improve the quality and expand the breadth of research for lifespan issues, for community living for autistic adults and employment, making it possible for rights support so autistic adults can gain access to employment in the community setting.

So I would like to see that as we move

forward how, you know, those gaps can be addressed.

Thanks.

Dr. Insel: Yes, thank you. So I mean, it's really hard not to notice as you go through the literature that you've got the two sides of this problem here. On the one hand, real concerns about coverage. And as David's paper points out, the disparity between public Medicaid coverage and private insurance. On the other hand, what we're hearing in so much of these, especially the reviews that are being published now is that the evidence base isn't there to know what should be paid for.

So we've got to think through this in a smart way to make sure that for payers, whether it's public or private, who are having to make tough decisions between cancer, Alzheimer's, heart disease, autism, that they understand that the evidence base, what it is, and that the criteria are in some ways showing parity with what we've got in the rest of medicine.

I think, you know, given where we are with time, I want to move on. We'll get back to a lot of this, I think, as the day goes on. I know many of you have strong feelings about some of these issues.

And I do think when we get to that business part of the agenda later in the afternoon that will surface some of these issues and think whether the IACC can have a role here.

The other tradition we have is the round robin. And we can't do everybody on the Committee each time. But what we've tried to do in the past is sort of have three or four people kind of give us updates about what their agency or what their foundation or what their group is involved with.

And these are often rather brief, but it's just a chance to kind of catch up with what's going on in the community. A couple of people had written in and said they would like to do that.

Geri, you were going to speak a bit. And if there's time left, I think we've got a few others, as well.

Dr. Dawson: Great. Thanks for the opportunity. I'll try to be as brief as possible. I did want to point out that this fall, in a supplement to the journal *Pediatrics,* which is the flagship publication of the American Academy of Pediatrics, there was a review of medical conditions that are associated with autism as well as the first empirically based physician guidelines for the assessment and treatment of sleep, GI problems, and ADHD in children with autism.

So we're really excited to see that, and we'll expect to see more of those guidelines published in the future. I wanted to mention that Autism Speaks held its first annual professional and family conference in Columbus, Ohio, last summer – very well attended, about half professionals, physicians, psychologists, other health care professionals, and about half families.

And we are going to be doing this on an annual basis. We offer continuing medical and educational credit, and our next conference will be in July of 2013.

We also launched a new nonprofit affiliate to Autism Speaks called “Delivering Scientific Innovation for Autism,” or DELSIA. I am the Chief Executive Officer of this nonprofit affiliate, and Rob Ring is the President.

And this affiliate will be partnering with for-profit companies to facilitate the development of medicines, technologies, devices, and services that can improve the lives of people with autism.

I wanted to mention also, in the same vein, that we'll be holding our first autism investment conference next month in New York, where we're going to be bringing together people with venture capital that would want to invest in biotechs, other kinds of companies that are developing products that can improve the lives of people with autism.

We funded close to $7 million in science grants since we met as a group and $450,000 of community grants. And we also distributed 840 iPads to families and provided financial help to 3,000 families in crisis, including families affected by hurricane Sandy.

And then finally, just a few updates about the insurance coverage issues – very timely in terms of our discussion. I wanted to mention that TRICARE now has created a 1-year pilot program that's going to be expanding ABA to all military families.

We see that as a success and a movement in the right direction. And also ABA will now be covered for Federal civilian employees by 67 out of the 230 plans that are offered by the Federal Employees Health Benefits Program in 2013.

On a less positive note, I want to point out that less than half of the states plan to include a behavioral health benefit for autism in the new health care exchanges that are part of the Affordable Care Act.

And I think this is a very serious concern that the IACC, as the Federal agency that oversees services for people with autism, should take on and provide advice around this issue because clearly, people are not going to be able to benefit from the services that we do know are helpful.

Dr. Insel: Great. Thanks, Geri. The other person who had written in was from the Administration for Community Living, Sharon Lewis, who is not actually with us.

But I think that Ophelia McLain is representing her and may be on the phone? Yes, no? Ophelia, are you there? I guess not. Other comments? Scott?

Mr. Robertson: So I just wanted to share briefly some updates on the work of ASAN, the Autistic Self Advocacy Network. We held our first leadership training academy through our autism campus inclusion project last summer at the National Federation of the Blind's conference center and trained, during a weeklong workshop, trained leadership skills, self-advocacy skills, and campus advocacy skills to 18 autistic college students, who had applied competitively from schools nationwide.

And now back at their college campuses, they're working to make their campuses more inclusive and supportive of not only autistic students, but other students with disabilities, and hopefully can engage in more leadership on engagement and systems change around disabilities and autism as they move through school and graduate.

And we will be holding our second one this coming summer, actually. We have our call for participants out right now to train another second cohort of autistic college students.

ASAN also became recently, a few months ago, started a collaboration on a partnership on two new federally funded national centers on employment.

They're funded out of the Office of Disability Employment Policy and the

Department of Labor – one on advancing employment and one on technology accessibility and technology use in employment settings for people with disabilities.

And I would be happy to share more details of that over email with folks and more specifics on the two different centers.

And related also to college employment is that we have not only a book on college out there, but we also have some other resources that will be coming out in 2013 and 2014 on employment and college.

And then related to health care services, we have some research that is finishing up that has been funded under a grant for the National Institute of Mental Health that is related to accessing health care services by autistic adults that I think will prove very helpful for the community for understanding and the access by autistic adults to health care services.

Thank you.

Dr. Insel: Great, thank you. Jan?

Ms. Crandy: I was wondering if I can ask Geri some questions on some of your comments that you had made, if that would be okay?

Are you finding that states that had the autism mandate passed for insurance are not being included in the exchange? And are you having questions about the limitation of number of visits coming through because of the caps being lifted?

And then, what reports are you getting back from states, now that these mandates have passed? Is it really working? Is coverage happening and at the degree it should be?

Dr. Dawson: I can answer those, but I also have people in the audience that have a lot of depth of expertise on this. So can I refer to them or not, because otherwise I'll –

Dr. Insel: Yes, I mean, well, let's just see how many other round robin comments there are. If I can get a show of hands of other people who want to do updates. So John. Anybody else? And Walter.

So why don't we take a couple of minutes and hear about this, Geri, and then we'll go on.

Dr. Dawson: Yes, because I think this is really important. And Stuart, you're here, right?

Mr. Stuart Spielman: Yes.

Dr. Dawson: So can you speak on this because I think I can provide the big answers to those, but he really knows the details on it.

Dr. Insel: Yes, Stuart, we'll need you to use a microphone. Thank you. If we can make this brief because I think we'll come back to it, actually, later in the day.

Mr. Spielman: Okay, I'll be very brief. As Geri indicated, what we're seeing is that roughly half of the states appear, and I say appear because the situation is somewhat in flux.

We don't have final regulations out yet

on the essential health benefits to have a behavioral health benefit. At one point, we were hoping for consistent, nationwide coverage.

And at this moment, that's not yet happened. So there is definitely a gap that needs to be addressed.

Dr. Insel: Can we ask you to mute your phone. I think it would be better for everybody if you could. Thank you.

Dr. Burton-Hoyle: Can I say, in Michigan, we passed our autism legislation last year. And it's so convoluted that only two people through the autism legislation insurance have been able to get services. There's only two.

Dr. Dawson: So there are, I think, some states that have done a really good job at detailing, you know, the kinds of services that people should receive.

And I think there are ones that we would hope would be precedent setting. Many of them are very vague. They're open to interpretation. They don't necessarily specify autism.

And so then, you know, even if there's a behavioral health benefit, when you try to use it for autism services such as ABA, they're being denied.

So you know, I think it is a huge concern. And I think the IACC could play a leadership role in this.

Dr. Insel: Yes, let's bookmark this because I think we do need to come back to it. It's clear that what we've been doing since last July is, you know, racing to get the update of this research plan done before December, and that's done.

But even in the course of doing that, we kept hearing from everybody we need to focus on the disparities in services; there are so many regional differences; there are so many things that need to be taken on here.

So let's plan to circle back to this in the afternoon, and we'll have more time to really dig into it. John, you had your hand up for a round robin comment?

Mr. Robison: Yes. I would like to revisit the issue of the social communication disorder.

In our IACC meeting in the summer, we heard a presentation from Sue Swedo, in which she showed us in her slides that the number of people captured with diagnosis in the new *DSM* definition set was approximately the same as the number of people captured by *DSM-IV* autism criteria.

And that was evidence that the idea that many people would lose a diagnosis was not right. I didn't understand it at the time, but I now see that her numbers showing that a similar population was captured included those people who were captured via the social communication diagnosis.

Now I take that, on reflection, to mean that she intended social communication to be a part of the autism spectrum, “autism lite,” if you will.

If we're here talking about autism and she makes the representation that the people are captured by the new diagnosis and that's one of them, that seems to me the logical way to interpret it.

She's not here to answer that question in person. It's caused a tremendous amount of concern in our community because people are worried about the educational interpretation of *DSM*, which we don't talk about very much here.

But the fact is that school districts now, if they see a person has a social communication disorder diagnosis and social communication isn't definitely part of the autism spectrum, those kids may not ever receive what used to be an Asperger's set of services that the school district would give the children.

And we sort of countered that by saying well, services will evolve for kids with social communication disorder. But if it's not clearly defined as part of the autism spectrum, it may take 5 years for that to happen.

And we on the IACC should take a position about that. And I have a specific idea that I would like to throw out to you. Now that *DSM-IV* is done, *DSM-IV* is a publication which really influences clinicians here in the United States.

Everywhere else in the word, the standard document is *ICD*. And indeed, here in the United States, it is *ICD* coding that drives all of our statistical reporting of disease and disorder.

Now the ICD Committee, which is part of World Health Organization, is now working on *ICD-11*. And as part of that, autism will be redefined there as well.

There's a fundamental difference between how the two groups have approached it. In the American *DSM*, each condition was a stand-alone thing with a name and a code number.

In *ICD*, they have something they call the pervasive developmental disorders. And that includes autism, Asperger's, Rett syndrome, childhood disintegrative disorder, PDD-NOS.

So the *ICD* construction already provided for all these things to be integrated together as the *DSM* folks attempted to do here last year. It's a relatively simple matter, then, for us to make a suggestion to the *ICD* Committee that social communication disorder simply be one of those subsets of the pervasive developmental disorders.

And if the *ICD* Committee were to agree with that recommendation and they were to make that decision going forward, that would be a very strong, positive step to define social communication disorder as having a continuing place on the autism spectrum, and therefore kids with that disorder would clearly be entitled to the same sorts of services kids with Asperger's would be in the past.

Now, the *ICD* Definition Committee is made up of members from all over the world. The members, to the best of my knowledge, from North America are me, Sue Swedo, who chaired the *DSM* Committee, and Lonnie Zwaigenbaum, who some of you know from other autism committees up in Canada.

And I believe this myself. I don't know what Sue believes. I haven't talked to her about it.

But this is my first chance to throw this out at the IACC, and I would like all of you to maybe have that in mind as to whether our Committee should make such a recommendation with the delivery of educational services in mind, separating that from any medical or psychiatric questions. So that's my thing for round robin.

Dr. Insel: Okay, thanks John. And too bad that Sue isn't here. I did talk to her yesterday because this has come up from others, as well.

Her comment was interesting.

She said actually, she thought that the social communications disorder group that worked on this had brought in people from the services sector from the get-go.

And actually, they were looking at this in a somewhat different way. They thought that it was more likely the services would be presented and provided to people with that diagnosis than people within the autism spectrum perhaps because social communication, according to her, fell very close to aphasia, which is always covered pretty densely.

So it might be worth bringing her in or bringing her back, or we could even set up a conference call to hear from her more directly about what was done and where the evidence is for that.

When is the meeting of *ICD* so we would know what the IACC could do?

Mr. Robison: The Steering Committee will meet for the first time in Stockholm a week after IMFAR. So I think the 10th or so of May.

And with respect to your conversation with her, I've talked to her before about this, like, at IMFAR last year. And I believe that she's certainly well intentioned and didn't intend for there to be a denial of services.

But the more I've learned about the operation of regulatory groups and insurance in our country, the more cynical I have become.

And I now really believe that any change that takes it out of the autism spectrum is simply a good solid reason for a denial of service until the Government proves otherwise. And that could take us years. And I don't think we have years in this case, and we need to be very conscious of that.

Dr. Insel: Great points. Good, okay. Well let's, again, I think we'll circle back to some of these issues later in the day, as well – extremely important.

Walter, you had your hand up. And then after that, we'll have to move on.

Dr. Koroshetz: Okay, real quickly I just wanted to mention that, you know, I think there was a report at the last meeting or the one before about epilepsy in autism, a workshop that was held at NIH. And there are two new projects now coming out. Mustafa Sahin at Boston Children's Hospital is going to be looking at early biomarkers of autism, concentrating on MR and EG.

And he's coordinating with another group out of, I think it's Alabama, that will be looking at EG in tuberous sclerosis patients with the idea of – this is a pilot for a second-level study looking at mTOR drugs in preventing epilepsy in TS, tuberous sclerosis patients.

We funded a study by Diane Chugani at Wayne State looking at buspirone, a serotonin agonist, in autism. That study has been completed, and data is under analysis.

We also fund the Autism Birth Cohort Study in Norway, which is a population study of over 100,000 infants, with data taken from their mothers during pregnancy, the babies.

And they are on track to recruit; there

are about 500 cases now. After having trouble in the beginning, they seem to be on track. And they actually will have some very interesting data coming out in the next month or so.

Dr. Insel: All right, thank you. Before we move on, any other urgent things that anyone needs to share with the Committee?

Dr. Koroshetz: Well, there's one thing I wanted to mention. The Academy of Neurology is putting out guidelines in the treatment of autism of both medical and behavioral. And they have open comment period until February 24th, so I'll send that –

Dr. Insel: Yes, I think it would be good if we could get the link. And Susan can send that around because many of us probably didn't know about that.

Okay, anybody else from IACC on the Academy of Neurology Committee? You're not on it, Walter? Deb? Okay, so Deb Hirtz from NINDS. Good.

All right, let's move on with the agenda.

Some of you will remember if you were here in the previous IACC that Idil Abdull came to us for public comment before you were on the Committee to talk about concerns with the prevalence of autism amongst Somalis in Minneapolis.

And there was an intense discussion thereafter, and then a group got together from Autism Speaks, CDC, and NIH to launch a study.

And this is an opportunity now a couple of years later to hear an update on that study from Amy Hewitt, who is the Director of Research and Training Center on Community Living at the University of Minnesota and Marshalyn Yeargin-Allsopp, who is the Chief of the Developmental Disabilities Branch in the National Center on Birth Defects and Developmental Disabilities at CDC.

So Amy and Marshalyn, Marshalyn, you're going to start? Okay. Whatever you're most comfortable with. You don't have slides, is that right? So if you would like to sit at the table – whatever you're most comfortable doing. We're, as you can tell, relatively informal. Welcome.

Dr. Yeargin-Allsopp: So thank you very much, Dr. Insel, and good morning everyone. So as Dr. Insel said, we're going to provide an update to the IACC on the Somali Autism Surveillance Project in Minneapolis, Minnesota.

And as Dr. Insel introduced me, I'm Marshalyn Yeargin-Allsopp. I'm the Chief of the Developmental Disabilities Branch in the Centers for Disease Control and Prevention, National Center on Birth Defects and Developmental Disabilities.

I'm also speaking on behalf of our funding partners, which includes NIH and Autism Speaks in addition to CDC.

Today, Amy Hewitt, who is the Principal Investigator at the University of Minnesota, will give you a brief overview of the project, including successes and challenges faced thus far and future steps related to the project. So I'll turn it over to Amy.

Dr. Hewitt: Thank you, Dr. Yeargin-Allsopp for that introduction. And thanks to the IACC for giving us the opportunity to give you this brief update on where we are to date with the project.

I would also like to take a moment to introduce my colleague, Amira Adawe, who is sitting back here who serves as our community leadership liaison on the project.

About 5 years ago, as you heard, concerns arose in a Minneapolis, Minnesota, community about the unexpected high number of Somali children in preschool programs for children with autism.

In a response to these concerns, the State of Minnesota’s Department of Health conducted a study. And that study found that the proportion of Somali children enrolled in that autism preschool program was about two to seven times higher than that of non-Somali children.

The difference decreased markedly over 3 years, the t3 years that were examined. And based on national estimates, the proportion of Somali children in the Somali preschool program during all 3 years examined was similar to what would be expected, while a proportion of non-Somali children in the program for children with autism was lower than would be expected.

The Minnesota Department of Health study, however, had a number of limitations. One was including the reliance of language spoken in the home as the primary method to define Somali status and the inability to link birth certificate records to the children.

Another limitation of the initial study was excluding children who did not attend the Minneapolis public school program. So this was only conducted in one school program. Despite these limitations, the study was an important step toward understanding autism prevalence in the Somali community.

As Dr. Insel noted, in October of 2010,

Idil Abdull, a Somali mother and advocate, who now serves on the IACC, spoke to the IACC meeting to express her continued concerns about the number of Somali children with autism living in Minneapolis.

And as has been stated, in response to that, CDC, NIH, and Autism Speaks funded the University of Minnesota through a competitive announcement from the Association of University Centers on Disabilities to estimate the number of children with autism living in Minneapolis and to examine whether autism is more common among Somali children than non-Somali children.

The study methods that we adopted were developed by CDC and are used by the Autism and Developmental Disabilities Monitoring, or ADDM, Network.

Specifically, the ADDM Network reviews health and special education records to identify school-age children with autism. Data collected using this method can help explain if certain groups are more likely to be identified with autism than others.

Data collected using this method are also ideal for this type of project since the data come from multiple sources, in this case, education and health records in the community and from multiple sources in the community.

And autism status is independent of specific ASD tests or diagnosis, which can be delayed or overlooked, particularly among children from different cultures.

Thus, results can be used to promote awareness of autism in different communities, help those communities plan and coordinate service delivery, and inform future research and advocacy efforts.

We were initially funded for 1 year to encourage a timely response to community concerns. Because the State of Minnesota didn't have an existing autism-monitoring system in place, we really had to build infrastructure for autism monitoring from the ground up.

This is a very time-consuming process, and much of the process relies on developing relationships with community partners, including all of our data sources in education and health clinics.

As such, building these partnerships was an integral first step to our project. We had many one-to-one meetings with our data sources, including health and special education programs, charter schools that serve large numbers of Somali children in the Minneapolis area.

And in those meetings, we explained the importance of autism monitoring and this project in particular. We wrote and submitted a number of applications to obtain appropriate approval from these partners to begin a data collection.

We also obtained public health authority from the State of Minnesota that allowed us access to clinical records for the purpose of monitoring autism prevalence.

All of these activities were conducted

within the first 8 months of the project, and data collection began soon afterward.

Because building this infrastructure took so much time and resulted in delays, we requested a 1-year cost extension for the project to complete the autism-monitoring activities. This cost extension was approved in March of last year.

Another important component of our activities is community engagement initiated by our project staff, which is not typical in other ADDM Network sites.

We've engaged the community in a number of ways by establishing a community advisory board, hiring Somali community facilitators, hiring a Somali leadership liaison person, and conducting outreach through community resources and meetings and through immigrant media sources.

The community advisory group and community facilitators are comprised of Somali parents, autism advocates, health care professionals, and other individuals in our

Minneapolis community, who are deeply concerned and care about autism.

And the results of our project … they provide important information to us on cultural issues and encourage better understanding in the Somali community of the project from start to finish.

One out of five of our data collectors are also from the Somali community. In the next couple of weeks, we've reserved a community advisory meeting, that's specifically to listen to parents share their stories about their children with autism and other community members who will tell their stories about how autism is affecting their communities and how they see it affecting the Somali community in particular.

Many of these reports will be shared in our community report once our findings are summarized. Moreover, after listening to the community and their concerns about disparities, we added additional research questions that will address potential differences in the level of functioning and service delivery between Somali and non-Somali children.

Thus, we and our funders believe that attempts to hire and engage members of the Somali community have been significant throughout the duration of our project.

As previously mentioned, CDC's ADDM Network methods are being strictly adhered to in this study. And just as a refresher for those who might not know what these methods are, they require many steps to ensure quality and accuracy. And I want to take a moment just to review those.

Number one, preparing a detailed proposal, which we did. And that was reviewed by a team of experts through a peer-review process.

Obtaining institutional permission for the study. Three, hiring and training qualified individuals as a part of the research, as well as our community teams.

Four, developing partnerships and gaining access to health and special education sources that provide us with data.

Five, developing partnerships and engaging in and with the community as much as possible.

Six, collecting data from health and special education sources.

Seven, checking the data for quality and accuracy.

And eight, conducting a detailed analysis.

The standard criteria used as a part of the ADDM Network methods ensures that all records are evaluated and reviewed in the same way and all children are defined as having autism using the same definition.

CDC, NIH, and Autism Speaks have monitored our efforts throughout the duration of this project to ensure adherence to the CDC methodology.

Our project coordinator has weekly meetings with the CDC project coordinator, and we send weekly written updates to CDC, NIH, and Autism Speaks on our progress.

Our leadership team, which includes myself, the project coordinator, two other researchers on the project, and our Somali community leadership liaison, also have monthly calls with all of our project funders.

For this project in particular, CDC staff have also monitored some of the data collection in Minneapolis to add additional verification of our results. For instance, the CDC conducted a site visit in November of last year to review study progress and monitor study methods.

During the site visit, CDC leadership met with project staff, attended a community advisory meeting, spoke with members of the Somali community, visited several health and special education partners, and reviewed our data collection process.

There were no major concerns noted from the monitoring efforts, and all of the recommendations from the site visit have been addressed. Our next step is to finish the data collection and review and prepare the data for analysis.

Colleagues from the University of Minnesota, the Minnesota Department of Health, and CDC will all assist with the data analysis to ensure accuracy of our results.

We've also established a communications workgroup that's going to work together to prepare our community report that summarizes our findings in a way that's understandable and useful to families and can be disseminated in the Somali community as well as the larger community.

We plan to release that report this summer. So in summary of this short update, the application of CDC surveillance methods, without an existing infrastructure for monitoring autism prevalence, has definitely been challenging and time consuming.

However, substantial progress has been made, and we are adhering to the CDC methods to ensure accurate and unbiased results. The amount of community engagement has been exceptional, and we view it as an essential component of this project.

We believe our autism surveillance and advocacy efforts depend on continued communication and collaboration with the community that this work impacts. We are therefore working with everyone to ensure the project is a success.

Dr. Insel: Thank you very much.

Dr. Yeargin-Allsopp: Tom?

Dr. Insel: Yes, go ahead.

Dr. Yeargin-Allsopp: I have a few concluding remarks.

Dr. Insel: Sure.

Dr. Yeargin-Allsopp: Okay. So we agree the success of this and future projects will be enhanced by communication and collaboration within the community. All voices within the Somali community must and will continue to be an integral component of the project.

Not only will this project help us understand how often autism occurs in Somali and non-Somali children in Minneapolis, but results could also promote awareness of autism, help plan and coordinate service delivery, and inform future research and advocacy efforts.

We would like to thank the University of Minnesota and our partners at NIH, Autism Speaks, and the Association of University Centers for Disabilities for their work on this project.

I would also like to publicly acknowledge the tremendous leadership of Lisa Wiggins, the CDC's science lead for the project, who is here with us today.

And of course, we would also like to recognize the children and families living with autism in Minneapolis who inspire and motivate our work. Thank you very much.

Dr. Insel: Thanks to both of you for coming and giving this very comprehensive update on the process. But just to be clear, are there any results at this point, because the reason this got going in 2010 was because people said hey, we may have a cluster?

Dr. Yeargin-Allsopp: I'll let Amy -- Amy should answer.

Dr. Insel: Is there a cluster?

Dr. Hewitt: There are no results to date.

Dr. Yeargin-Allsopp: And I know that it's very difficult without PowerPoint, and maybe people got lost in some of the specific information.

But there will be a report this summer. So this is an interim update for the IACC. So expect a report, which will be a scientific report and a community report that will be available later this year.

Dr. Insel: Alison?

Ms. Singer: There are no preliminary findings that you can share with us? If the report is going to be ready in the summer, there are no results to bring to the table?

Dr. Yeargin-Allsopp: No, because to my knowledge there had been no report back to the IACC since we were charged with doing this. So in terms of the methods, in terms of the progress, we just thought that it was important to do this in a preliminary way so that you would be prepared for the results when they're available. We do not have preliminary results at this time.

Dr. Insel: Dennis?

Dr. Choi: Are there any plans to profile Somali communities elsewhere? Somalia or other U.S. cities to provide context?

Dr. Yeargin-Allsopp: I guess in some ways you're asking about not just generalizability, but additional efforts related to the Somali community. And I would say there are no plans because we don't have resources to do that.

Dr. Choi: And you know better than me. I mean, I'm interpreting whatever you find in Minnesota or whatever is going to be much more valuable if you had the other comparative.

Dr. Yeargin-Allsopp: I agree.

Dr. Insel: And there was a study

published from Sweden or Norway. Maybe somebody can speak to that? Sweden?

Dr. Yeargin-Allsopp: With three children. It was a very small study. And we don't feel like it's generalizable at all. So there have been a few studies. But again, I think that this will be using different epidemiological methods and probably more, I guess, reflective of what's actually happening in the United States today.

Dr. Insel: Matt?

Dr. Carey: I mean, I think this kind of goes along with what Dennis had to say. It seems like you've built a pretty good tool at, you know, considerable effort.

And to see that end, you know, with this, unless it's very conclusive, I mean, to see it end seems a shame. My guess is you're probably not going to disagree with that. But it's going to depend on funding.

Dr. Yeargin-Allsopp: I won't disagree, but I'm bringing it back to this body because you asked a very specific question. And we will answer that question.

Dr. Insel: So Marshalyn, I guess one of the questions that people will want to know is if we can fast forward 6 months and so just the hypothetical. If you find no difference, what do you do with that? If you do find a difference, what do you do with that? What's the next step based on? I think there are only those two potential outcomes here.

And we got into this with a lot of enthusiasm now almost 3 years ago based on the sense that this could be an epidemiological cluster, which we have not had in that respect in the United States. And so people thought this was extremely, not only important but urgent to try to get our hands around. So a sense of how to deal with the results based on what comes out?

Dr. Yeargin-Allsopp: Well, first of all, we do have a communications workgroup that is going to take the results, regardless of the results, and make them very understandable to the community and to the public at large.

Regardless of the results, we think that it's important to establish whether the prevalence is higher in Somali children in Minneapolis.

And we know that from the initial report from the Department of Health that there has been some misinterpretation of some of those results.

So for example, we often hear that the prevalence is higher in Somali children in Minneapolis, and we really don't know that from a population perspective.

We know that there were more children attending the preschool program, but we also know that there was an under-ascertainment of children of other minority groups.

So just from an epidemiologic standpoint to understand whether the prevalence is higher or not is extremely important.

But I think it has tremendous implications for the community because I think that understanding the prevalence will also help in terms of provision of services.

It will also provide the opportunity to talk about maybe understanding what causes autism in this community. But those are next steps. And those questions are not able to be answered with the limited funding that we had for this activity, as you know, Tom.

Dr. Insel: Okay. Idil?

Dr. Burton-Hoyle: What was unusual in this study was not only how comprehensive it was; the underpinnings of how it is that you were supporting family members in the community was there, which is not in other kinds of cold, you know, just-get-the-numbers sort of study.

So I think that when you get those, whatever the results are, you will have created a network of supports within that community in Minneapolis, which I think is rare and I think it's really wonderful, and I love that in the design.

Dr. Yeargin-Allsopp: And I would also like to add that, because of community concerns, we did add a question related to the severity of the symptoms in the children because that's one of the things that we've heard a lot about as sort of characterizing these children.

Not just do they have autism or not, but is there something unique about their presentation? So we have tried to expand our initial methods to incorporate some of the community concerns.

Dr. Insel: Idil?

Ms. Abdull: Thank you so much, first of all for you guys for being here. And thank you again for the IACC people that were here in 2010 for letting me harass you a little bit to get this going.

And you know, as a parent and also as an advocate, I have to say I am excited, but I'm also sad because I know that we don't have results. And I thank Amy for doing all this comprehensive and including the communities.

But I have to tell you, one thing Somalis are good at is the ability to talk.

And autism has silenced us. There is no adult Somali person from Somalia that was born in Somalia that is 20, 15, 30 that is not talking.

There are hundreds of Somali children in Minnesota that are not talking. And if I can put on my pissed-off mom hat, it’s that so many people are saying “Oh Lordy, have mercy. That American government is just like the Somali government. They are going to tell us no problems, shoo, shoo. Autism is just the same as everybody else.” And a lot of them are not participating because of that.

And I want to believe that little immigrant girl that said I'm going to go to America because that's where the government is of the people, for the people, by the people. And I want to believe that, but when I talk to moms and dads that have two, three children with autism, this ain't no day at the park. We are suffering. These children are nonverbal. They're classic.

So I really want to just emphasize and

ask the Centers for Disease Control and Prevention to not always say we don't have resources but figure out a way to help all people with autism and to figure out a way that – because we're all here about this condition – to figure out a way, there's something happening because then it will help everybody in this table, whether you are a relative or researcher. There's something wrong in Minnesota.

Dr. Yeargin-Allsopp: Let me just respond to that and say, Idil, you know how much we thank you and appreciate all that you've done.

And I think that this really is related very much to the earlier discussion about services. So I was really happy to hear the earlier discussion because I think we need to talk about services for all children that are affected, regardless of the prevalence of autism in the Somali children in Minneapolis.

Every single child deserves the services that they need in this country. And you know

I believe very strongly in that. So I think that we don't need to be anxious about the results because I think we need to focus on the services that these families and children, that they need.

Ms. Abdull: I'm sorry, if I could respond, Dr. Allsopp, I get it. The services for minorities suck. We don't need to ask Jack and Jill about that.

But the problem is if autism is increasing and if there's something wrong with the community or a society or people who are somewhat ethnically the same that didn't have it back home but they have it here, doesn't that open eyes for researchers?
I mean, a lot of these people funded because I said if you are a researcher and you want to know about autism, here's your answer. I think hopefully that's a sentence that got you. It's high.

So then when we know it's high, then it can open doors for other research to find out why.

Dr. Insel: So just if I can intervene. I think that's a conversation to have after June when we actually see the numbers because I don't want to get ahead of ourselves.

The reason the study is being done is to clarify the numbers. I see a bunch of hands up, and we don't have a lot of time. But Geri, you had your hand up – John, Scott, and I think Lyn. And then we'll have to move on.

Dr. Dawson: Well, just really quickly, when we funded this study and in our initial conversations, the plan was that if the numbers show that the prevalence is higher than one would expect based on the population rates, that indeed the next question is why.

And so that's always been the plan that, you know, if this is what is discovered, and we don't have the results yet, so we don't know, that's clearly the next step that would need to be taken.

I do think that this study, though, raises several bigger issues that we need to grapple with as the IACC.

And they have to do with the fact that there are these tremendous ethnic minority disparities and that we know very little about prevalence estimates, access to services.

And more importantly, there is a lack of services because many of the, whether it's the 100 Day Kit or it's the CDC “Learn the Signs,” they haven't really been translated or culturally adapted to not only this community, and this is for Autism Speaks, too, you know, but many different communities.

And this is something that we're going to really need to embrace is how do we reach all of these different communities with services, with materials, with the ability to recognize early and so forth.

So I think it's a bigger issue that the IACC needs to take on. And the Somali case is one case in that broader set of cases that we need to look at.

Dr. Insel: Great, thanks. John?

Mr. Robison: One of the things, you know, I spoke earlier about *ICD*. And *ICD*'s goal is to develop standard definitions for disorders for the world.

I heard, you know, just now from you the emotional allegation that there are many Somali children here that do not speak, and yet when you go back to Somalia, there are not a corresponding number of autistic adults, who do not speak.

You're shaking your head. That's not what you –

(inaudible comments.)

Mr. Robison: That's what you said? Okay. So okay, so I heard that, and I think about that in the context of the study that we're doing here.

And one thing that says to me is for us to truly answer her question – whatever the outcome of the study in Minneapolis, we would have to do a study of prevalence in Somalia to find out what it is.

And then to take that a step further, I

just would like to say to the folks on the IACC here that the more I travel around the world and speak about autism, when I go to other countries, the difference in how autism is defined and perceived in those populations among respected academics and medical people was at first, to me, shocking.

And I see what a big challenge we have with the *ICD* group. I just would say that there could be a dramatic difference between the stated prevalence of autism if we asked a group of Somalis, a group of Italians, or a group of Frenchmen, and the prevalence we might find if we were able to put a team with the CDC methods in that country.

But we can't do it because of the cultural difference. It's a big, big problem in the world and one where we need to be very careful about, first, not imposing our views on other cultures, but also we need to have a standard set of definitions.

Dr. Insel: Good point. Scott and Lyn – and then we'll come around and finish with

Alison.

Mr. Robertson: Yes, I would like to just share just a comment that I think that this does raise, and I would be interested to see the findings when they do come out in the summer, potential implications on access to services for youth and adults.

And me thinking about what this means for other populations of diverse ethnicities, racial backgrounds, cultural backgrounds, language barriers, cultural backgrounds, cultural competency in those communities and what this means particularly for research on these things.

And the research is pretty scarce on these diverse populations in the autism community having access to supports and services.

This was actually mentioned as one of the comments by my colleague Ari Ne'eman at the House hearings on autism last fall on how we know that there's not necessarily equal access to service and support resources for autistic adults and youth among diverse communities, cultural, linguistic, et cetera.

But we particularly don't have really good research on why those gaps exist, what we can do to change those gaps, what we can do to address those areas and make sure that folks have access to not only a more level playing field of diagnostic access for supports, but also supports and services across the lifespan for folks of different diverse backgrounds and how culture competency, language issues, et cetera, fit into that area of making sure that folks in those areas, and also throwing in folks in rural areas who also, again not great research on that extensively, but we do know that's a problem that a lot of folks, for instance, in rural areas of different socioeconomic backgrounds don't have access to supports and services.

So I think this study may be hopefully one of many coming in the future that can raise some implications about what we need to expand, be thinking about how we have a priority to expand service supports in this area of folks in diverse population groups.

Dr. Insel: Good point. Lyn?

Ms. Redwood: Yes, I'm a little confused, because when Idil first came to us several years ago about this concern, as a Committee I felt as though we thought this could potentially be a cluster.

And from what I'm hearing today, the type of research that was done was essentially just counting the children to determine prevalence, where I think at this same time, I was also expecting that we would get some demographic data, we would possibly get exposure questionnaires, and it might give us more information about what could potentially be causing this.

So I just want to find out if all we're going to get this summer is just numbers, or are we going to get any additional information of what may be driving this, because my assumption was to take what we were told at face value and to try and understand it more than just ascertain the numbers.

Dr. Yeargin-Allsopp: This study was never designed to look at potential causes. It's just to understand whether the prevalence is higher in Somali children compared to non-Somali children.

And there will be a description of the children and families, but there is no component to look at possible environmental exposures or other exposures or to get at the question of potential causes. And that was pretty clear in terms of the charge from the IACC.

Dr. Insel: Alison?

Ms. Singer: Okay. That's shocking to me, because I was under the same impression as Lyn, that we were going to get some additional information.

So given that the results of this study are going to be either A or B, there's either going to be a difference in the prevalence or there's not going to be a difference in the prevalence, can we start now? Can we start working in parallel to prepare for either of those eventualities? That if there's not a difference in prevalence, then maybe we can say there's no difference. But if there is, can we begin to set up some of the infrastructure now to ascertain exposure data, to start to collect genetic materials so that we don't have to wait another 2, 3 years for that additional information? Because I understand that these things take time, but it is so frustrating to hear this update and have it just be about the process.

Dr. Yeargin-Allsopp: And I think you're asking the question of yourselves. I mean, it was the IACC that came up with the plan. So I think that that might be a conversation among the IACC members in terms of what you would like to do as next steps. So I'm turning that over to Tom.

Dr. Insel: Well, the question for the funders – so that’s CDC, NIH, and Autism Speaks – and I suppose that all of this hinges on knowing what some of the results are.

Even if we had preliminary numbers to give us a sense, I'm not sure, speaking for the NIH side, that we want to push forward without any suggestion that there's a real effect here.

I guess I thought today we were going to find out that there was a real effect and then we would have the discussion about what to do about it. But we'll have to sit on our hands another few months.

Given the sense that we have from what I heard, Amy, I think what you described, if I've got this right, is that the analysis of the earlier data suggested that the difference was not due to a higher prevalence amongst the Somali kids, but at a much lower than expected prevalence amongst the non-Somali kids.

Given that as the one piece of result that we have, I don't hear that there's a lot of energy there to go after a cluster. But let's wait. This is January. You said by June, is that right?

Dr. Yeargin-Allsopp: We said this summer.

Dr. Insel: This summer.

Dr. Yeargin-Allsopp: We said this summer. We can't be more specific than that.

Dr. Insel: Well you know, it would be great, the sooner the better, at least to get some preliminary picture.

I think what you're hearing from this Group is some frustration that, 2 years in, we still don't really have a picture of what's going on, whether there's something to pursue here or not.

And as Lyn brought up, the original concept was that if this turned out to be a cluster, which all of us thought was likely enough that we said, gosh, we've got to pursue this quickly, then the reason that's important is because it tells us that you have a whole exploration to do around the drivers.

And so you certainly would want everything from exposure data to genetic data to a lot of family history data to be able to inform that process.

So I think maybe the state we're at here is to make sure that Autism Speaks and NIEHS and CDC, that the program folks for each of those places, hear this concern, put their heads together and think about what to do between now and we'll put summer in quotes, but hopefully it will be early summer, not late summer when we get the results.

I do understand the reluctance to throw a lot of resources at something until you know there's a something to throw it at. But certainly we got into this because we were so convinced from what we had heard that there was a real finding.

I'm getting the sense from those of you who are deep into this that maybe we should just hold off before we think about the next steps. I'll give Cathy the last word, and then I think we do have to move on, given the time.

Dr. Rice: I think it's important to remember one of the strengths of this Committee is that we do have representation from a lot of different etiologic studies that are happening around the country and the world.

So hopefully, in the event that there is a finding, that resources really need to be focused on looking at the uniqueness of this community in terms of etiology, then hopefully we can start with some of the experiences we have from the NIH-funded studies, Autism Speaks, CDC-funded studies that have tried to pull together this very diverse range – so maybe thinking along those lines of how can we leverage the infrastructure we've already established in etiology rather than starting from scratch.

Dr. Insel: Yes, I got that. I think what you're hearing though, from the Committee, Cathy, is just this shouldn't take so long. That you know, this was, even now, as construed as a narrowly focused question just about prevalence.

If that's the only question that's being answered, it's hard to imagine why it takes many, many years to come up with those numbers in one site for a group that's so experienced.

Dr. Yeargin-Allsopp: Tom, I do want to comment on the timeliness of this. I can't help but say that those of you who are familiar with the ADDM Network know that it takes more than 2 years to get results where there is an established infrastructure, and there was no established infrastructure in Minneapolis. So I think that the University has done a phenomenal job at getting results to this point, given all that's required to establish relationships within a community to get access to records.

And I don't know if any of you are involved in that activity. Is anyone in this room, other than Cathy, me, Lisa, and now the University of Minnesota, maybe David, if you've ever had that experience, then I cannot emphasize enough that this really is an incredible study.

And we would be doing well to get results in this summer. So I just am asking the patience of the Committee and the understanding of what it takes to get that one number. And it will be more than one number.

Dr. Insel: Okay, we're going to have to move on. Amy, Marshalyn, thanks so much for coming from pretty far away to get us up to date. And we'll look forward to getting results. And you know, summer in Washington because of global climate change, is coming sooner and sooner. So that may remind you that we will hold you –

Dr. Yeargin-Allsopp: October, Tom.

Dr. Insel: October will be the summer for next year, at this point.

We're going to move on to hear about, speaking of prevalence, autism prevalence in Puerto Rico from Jose Cordero.

Dr. Cordero – Buenos dias. Well, good to see that we have some bilingual people here. I'll thank you very much to IACC and the Committee to – I have an opportunity to present the data on prevalence of autism in Puerto Rico.

This is a survey that we conducted in 2011. And this is a project that, actually, the Graduate School of Public Health, University of Puerto Rico, have actually done on behalf of the Department of Health in Puerto Rico.

Let's see if I know how to move this. Okay, so this is going to be bilingual, so that's why you see topicos and then background survey, findings, and discussion.

And as sort of background, just to be sure we know where we are talking about – this is Puerto Rico. I'm not sure whether I have a laser here.

But where the arrow is, that's a tiny island. Thank you – 100 miles long by 35. And we've been part of the U.S. since 1898.

And our population is about 3.7 million, and we have about 40,000 births. We are having a major decline in birth. In 1990 we had about 60,000, and this last year we are down to 36,000.

Sort of a background: We have in Puerto Rico an Autism Coordinating Committee, sort of state level, that includes a multisectorial group from parents to groups that care for children and adults with autism.

It is led by the First Lady of Puerto Rico and co-led by the Secretary of Health. And in that process, the group realized, and rightly so, that there is no survey or data on what is the prevalence of autism in Puerto Rico.

The School of Public Health, we also sit at the committee along with Dr. Annie Alonso, who directs the Institute on Developmental Disabilities.

And we actually reflected on the different options from developing a surveillance like Marshalyn and others were describing for Minnesota, doing some kind of registry, or doing a survey – in this case a telephone survey.

Our decision was to move with the survey for two reasons. One, time, and number two, cost. The cost of developing an ADDM-style or CDC-style surveillance, it is fairly expensive.

So we wanted to start with what we were able to do. So the survey, we used the methodology of a National Survey of Children's Health and also used for the survey on children for special health care needs.

It's a telephone-based survey, uses random digit dialing. And it was directed at residential telephones, so it does not include cell phones.

In Puerto Rico, about 80 percent of households have a telephone in their households. Now everyone seems to have a cell phone, too, but there are some major issues in using that in survey methodology.

The study also looked at elevating the

health needs of children or individuals with autism, but I'm not going to present those data. So the survey was specifically children age 4- to 17-years-old.

And here's the survey. I just will add that we used the probability sample that ensured that every region of Puerto Rico, there are different health regions and they're served under Medicaid by actually different contractors.

So it was important to know by region the prevalence and also look at their health care needs. To conduct this, we did nearly 47,000 calls, which we found that nearly 25,000 were residential telephones. And among those, there were nearly 5,700 households that had a child and there was an adult residing in that household.

In those households, there were a total of 9,892 children. Of those households where there were a child and an adult, we asked about if there was a child with autism, and that came out to 147.

But in total, we had 154, and the reason is that there were seven households with two children with autism. From that group, we did an interview that really sort of focused more on the health care needs but also had details about the diagnosis of autism.

The rate of autism prevalence we found overall for the island was 1.62 percent or 16.2 per thousand. And these slides simply show that in its essence, every region had prevalence that was within that range of overall in Puerto Rico.

And northeast was a little bit on the low side, but still statistically was within the range. So in summary, the prevalence was 16.2 per thousand, or 1 in 62.

Using that data, we tried to develop estimates of population with autism. And the zero to 3 where we had assumed that it was going to be the same as those, the 4- to 17-years-old.

For the 17-year-olds and older, we actually had to deal with two different assumptions. One, that the rate of autism in Puerto Rico has consistently been higher than has been reported in the U.S.; another, that it actually was the same and has just increased.

And when we look at those two models, basically the total estimate still is about between 19,000 or 20,000 to 21.8 thousand.

Here we have how does this compare to the U.S.? And especially comparing to the National Survey of Children's Health, which basically I should have indicated that we used the same questions and also simply translated and adapted to Spanish.

And we tested that. So our rate is a little bit higher than what's reported for 2007. And using the ADDM Network report that came out in 2012, that its data for birth cohort of 2008, our rate is a little bit lower than Utah and New Jersey and around where it is set for Arizona.

Since our population is essentially Hispanic, actually 98 percent based on the census, we also look at – sorry about that. We look at also the Hispanics in the National Survey of Children's Health. And ours compared to that is a little bit higher, but could still be within the range given the confidence limits.

It is also a little bit lower than in New Jersey, but it is higher than Arizona, Utah, Florida, and overall in the U.S., but meaning Hispanics.

So that's, in essence, the findings. So the prevalence of autism in Puerto Rico for children 4- to 17-years-old in 2011 was 1 in 62, or 16.2 per thousand.

And the prevalence, in general, falls within the range reported for Hispanics in the U.S., but it's in the higher side. And there are differences in prevalence between populations; it's something that we feel needs to be evaluated. So that's my presentation. Thank you.

Dr. Insel: Thanks. Let's open this up to comments or questions. Cathy?

Dr. Rice: Thank you, Jose. When you asked the question, was it about current autism or were they ever diagnosed with autism?

Dr. Cordero: We had both. We had ever diagnosed, and we also asked currently. That's actually the way that it's set up in the National Survey of Children's Health.

And in essence, we had one child that difference in terms of it says, yes, I've been diagnosed with autism, but currently no, doesn't have autism.

Dr. Rice: Oh, so only one.

Dr. Cordero: Yes.

Dr. Rice: So the 1.62, that is based on the ever?

Dr. Cordero: The 16 is in those currently, okay?

Dr. Insel: Lyn?

Dr. Carey: Dr. Cordero, could you also break this out in terms of ages? Was there any trend in terms of the rates being higher in the younger children than the older children? Was there any attempt to look at it by age?

Dr. Cordero: Yes. It was a little bit even lower in the 4- to 6-year-olds. And then in the 7 to 8 were about the same.

It was a little bit lower in the 17, very similar to what you see in the ADDM surveillance of what's in the surveillance in Atlanta. So the way we interpret it is that the group 4 to 6 still has children that have not been recognized yet.

And the higher up, we can't tell whether that it's just lower, or whether in fact these are children that have not been recognized.

Dr. Insel: David?

Dr. Mandell: So congratulations on fielding this study. It's very interesting to note, so you're asking, just so I make sure I understand, from the National Survey of Children's Health, asking the parent, has a health care professional ever told you that your child has autism?

Dr. Cordero: Right.

Dr. Mandell: And I was interested in Cathy's follow-up question because in the U.S., when you say does your child have autism now, or are they currently, a substantial proportion of families say no, which raises some concerns about the extent to which they understood the question or how they're defining autism.

And so it's really curious to me that in Puerto Rico, only one family said they're not carrying it.

Dr. Cordero: Right.

Dr. Mandell: What do you think the implications are of that for the difference? Are they understanding the question differently? Is it that there's such under-diagnosis in Puerto Rico compared to other places that when they get the diagnosis that they really do have autism?

Dr. Cordero: Okay, very interesting question. We were surprised. We were expecting more based on the experience of the

National Survey of Children's Health.

And one of the things that we did, in addition to this study, we used a little screener that looks at questions about behaviors that could independently get to whether does this child meet criteria for autism.

And in general, everyone, including the one that actually said don't have autism now, would fit into the criteria. But the sample is too small to really go beyond that.

And basically, there were 131 that were interviewed. And that was sufficient to deal with the prevalence and to address some of the questions of health care needs.

But that is a question that we would certainly like to pursue. And we're hoping that we have a new administration and that we would go ahead and do another survey and probably do it larger. And that would be one of the key questions we would like to ask.

Dr. Insel: Yes.

Ms. Abdull: Thank you so much for

presenting this. I was just wondering, in just following what David had said, because in America, we always hear that autism obviously is about behavior, and behaviors in different cultures are different.

And Hispanic, similar to African cultures, a lot of the behaviors to social skills, the looking at you, eye contact, play skills – it's normal, right? It's normal to us, and whereas mainstream America, that's a characteristic of autism.

So I wonder when you guys were asking the questions, if you were asking about the behavior and social skills, or if you were concentrating more about the communication, or if one of you said does your child have autism, if the parent understood the whole concept of autism the way we define it here?

Dr. Cordero: Okay. For the purpose of this survey, whether the child was classified as having autism was based on the two questions: One, has your health professional ever told you that your child has autism or autism spectrum disorder? Okay? And then the second question of, does your child currently have autism?

Those are the questions. What I was mentioning about the screener is that we were interested in looking at how does that report connect to behaviors that are actually within the range of what autism is.

And just to go into more specifics, there are two studies – one done in Australia and one in Argentina that have used sort of a modified ADOS to actually get to that question.

And that's what – we use a set of questions from that. And I would be happy to talk more about that later, okay?

Dr. Insel: Walter?

Dr. Koroshetz: I was wondering, I was looking – there was a study that CDC did looking at autism in the Hispanic population in the U.S.

Dr. Cordero: Yes.

Dr. Koroshetz: And they found that if

the parents were born overseas, there was a much lower incidence than if the parents were born in the States.

The question I have is whether or not the CDC data has a cut on the Hispanics that originated in Puerto Rico to look at the question of whether or not moving to the mainland is associated with a higher incidence, because you have the data from Puerto Rico.

Like, we talk about Somalia; we don't have the data from Somalia. It's going to be hard to get data from Somalia. But here we have Puerto Rico data, and we have U.S. data.

Dr. Cordero: Yes. Marshalyn, is Marshalyn? Oh, here you are. And in the ADDM surveillance, is there a question about, or sort of the origin or birth of (inaudible) okay. Yes, it is available on birth certificate.

Let me just add, the paternal and maternal origin in terms of where the parents were born, it is in the birth certificate.

But it isn't in the birth certificate that you can easily access. You have to go through a process to get to that information, but it is obtainable. Now I'm not sure that there have been any follow-up studies on that.

When I saw those studies, my reaction was that the difference may be related to the level of recognition or how early these children were recognized for children that parents were from another country or would have come to the U.S. from another Hispanic country.

Probably there is a delay in recognizing that the child has autism. But that's my hypothesis. I don't have data to support it. Cathy. Oh, sorry.

Dr. Rice: Just a quick follow-up. So with the ADDM Network, there is a linkage to birth certificates if the child was born in the same area.

So it would be possible in areas that have a larger Hispanic community, like in

Arizona, as doing some follow-up analyses. And so the specific origin would be really interesting to follow-up on.

Dr. Insel: Scott?

Mr. Robertson: I was wondering, is there an intention for future research related to this to be doing some needs assessment to be looking at not just a prevalence in Puerto Rico, but more extensive looking at needs assessments on how, maybe, what service access looks like, supports access and the implications for that for, for instance, population of Hispanic group here in the United States and other kind of diverse populations across the country?

Dr. Cordero: We did. And we did a very extensive – we used also the survey questions of the National Survey of Children's Health.

I'm simply not presenting it here, but suffice to say, I can tell you that what we have, one, the needs in terms of health care services are much greater, as expected.

The second, we did find that children

with autism in Puerto Rico had a lot more concomitant conditions than generally have been reported in other countries.

Third, we had 98 percent of the population that actually had coverage, health insurance coverage, but both on the Medicaid side and the private, nearly 60 percent reported that they have to spend money out of their pockets to cover the services of individuals with autism.

And actually, it was a little higher in the private sector. And we have done some basic analysis of the health coverage for autism.

And part of the challenge is that the health coverage for autism in private insurance, it's quite limited. And so I think that that's just another, but I would be happy to come and talk about that later, in another meeting.

Dr. Insel: I'm concerned about the time here. But with your forbearance, we've got a couple of other comments.

Dr. Cordero: Okay.

Dr. Insel: So if people can put off lunch another few minutes, Matt?

Dr. Carey: Quick question. I think in the 2007 National Survey of Children's Health, I think the rate of people who responded their child was nonverbal in autistic, it was about 3 to 5 percent. I mean, do you know what the data is from Puerto Rico? I think my question's in there.

Dr. Cordero: I don't remember from the top of my head. I think it's a little bit higher than that in terms of nonverbal. But I would be happy to check that for you.

Dr. Carey: If you do find out, thanks.

Dr. Insel: Dennis?

Dr. Choi: Understanding the early nature of your methodology, I thought the interregional differences were quite striking, Utah versus New Jersey. And your last point that this is worth investigating, that was very important.

Have there been other ethnically defined populations in the U.S. where twofold differences in prevalence have been identified?

Dr. Cordero: Don't know. Maybe Cathy can answer that. But let me point out, I think that we need to be cautious. I put this as a reference, but there is a major difference in methodology.

The National Survey of Children's Health is a telephone survey, and ours, too. But the others are ADDM Network, and they're based on the methodology that Marshalyn presented.

They're 8-year-olds. And so it is from that you have to account for. So we are looking at different age groups and also looking at a different methodology of ascertainment of the cases.

Dr. Insel: Cathy, last comment. Do you want to say something about the ethnic differences from the ADDM Network?

Dr. Rice: Yes. I think it's something we need more data on. We primarily have data split out by white, African American, and

Hispanic. And then very small estimates in terms of Asian Americans, Alaska Natives, other groups.

And you tend to see, comparing black to white prevalence, you see differences depending on the site. In some sites, there are differences where prevalence is lower and some sites you see that it's similar.

And so it really seems to be more of an identification issue similar to the Hispanic group, in that over time, we've seen gaps closing and that Hispanic and black prevalence is rising at higher rates than the white prevalence, indicating some degree of improved identification over time.

Although it's not certain, I think the study that Walter mentioned where we looked at the National Health Interview Survey data showing the difference between two U.S.-born Hispanic parents versus two non-U.S.-born Hispanic parents showing the very big differences in prevalence. That's still an empirical question – is that an identification issue? Or there are questions about, as we've been talking among Somalis about immigrant status and increased risk for autism, you know, different infectious exposures, a variety of things that could be occurring in that situation. And that's really an open question that we just don't know.

Dr. Insel: I think that's a great point, maybe a good place to close. I think when you define this by ethnicity; you're taking a very gross and coarse approach to what is a really heterogeneous sample.

And particularly when you talk about Hispanics where you've got people who are, we know, based on other areas of medicine, just vastly different levels of risk and prevalence depending on whether you're talking about Mexican, South American, Caribbean.

I mean, it really does matter. So there'll be some finer details that would have to be worked out here. The good news is the ADDM Network actually has a fair amount of that data embedded in it. So it may be possible to go back to some of that.

And even as Cathy's implying, looking at the age of diagnosis, you can get some pretty good sense of what may be some of the drivers in the changing numbers because, as she says, that gap has really closed in the 2008 sample. That's probably the most striking difference from the previous samples.

We are at our lunch break. And I want to make sure that everybody's back here precisely at 1 o'clock because we have public comment at that point, which is a really critically important part of this meeting.

There's a cafeteria upstairs that you can use. And probably be best for people to remain close by because there's no other place to eat outside of this building that's nearby that you could get back within an hour.

Mr. Robison: Is the room secured so we can leave our computers, Tom?

Dr. Insel: Lina, is our room secure? She's shaking her head; the room is secure.

Dr. Daniels: The room is secure.

Dr. Insel: For those on the phone, we'll see you back or hear you back at 1 o'clock.

(Whereupon, the Committee recessed for lunch at 12 p.m. and resumed at 1:05 p.m.)

Dr. Insel: While we're waiting, you should have in your folders the oral comments that were scheduled for today from the public.

Mr. Robison: Is the plan that they're going to read the same thing that's written here?

Dr. Insel: There may not be time for that. So what we usually ask people to do is to take 5 minutes, and that's all we'll have for today because we have five different presenters.

There'll be time for us to respond later in the afternoon, as we've done in other meetings. But what we'll do is invite each person in turn to come and give us no more than 5 minutes of a precis of their comments.

And of course, all of you have the written version of this in front of you. Some people may choose to read them, that's okay. But we do have to keep to the time limit.

So let me ask, do we know whether we've got the Webcast up or not?

(inaudible comments.)

Dr. Insel: We're good. Okay, welcome back to those of you who are listening in or watching for the Webcast. The first oral public comment is from Amy Lutz. And you can either use the podium or come here and sit at the table, whatever you're more comfortable with.

Amy Lutz: Good afternoon. My name is Amy Lutz, and I'm the President of EASI Foundation, Ending Aggression and Self Injury in the developmentally disabled.

We support autistic individuals with dangerous behaviors and their families through our resource guide, our research projects, and our advocacy, speaking as I'm doing now, on behalf of parents, who can't stand before you themselves because their children require constant supervision to ensure they don't hurt themselves or others.

I'm sure you already know that aggression and self-injury are prevalent in the autistic population. Studies suggest that up to 30 percent exhibit these behaviors to some degree.

But because these behaviors generally isolate families and preclude their children's participation in the community, I wanted to show you what they actually look like. So I brought some pictures.

This is my son, Jonah pounding himself in the face when he was 10 years old. And this is a Colorado boy whose self-injury landed him in the hospital. And these cases aren't as rare as you might think.

I just don't have pictures of the young woman, who blinded herself after repeated blows to the head, or the teen who had to wear arm stays that literally kept him from bending his arms so he didn't do the same, or the young man who spent years in five-point restraints in a state hospital because his aggressive rages required six trained professionals to manage.

To give you an idea of the scope of this problem, there are 11 specialized inpatient units in this country for kids with developmental delay and dangerous behaviors, and that isn't enough. Many of these have waiting lists months long.

Research shows that aggression and self-injury are highly correlated to restraint, abuse, and institutionalization, and most obviously, a very low quality of life for afflicted individuals and their families.

Yet, this population is severely underserved. I would like to leave you with three action items I hope you will consider as you shape your Strategic Plan for the future.

First, simply recognize in the Strategic Plan that this underserved population of severely disabled autistic individuals exists and has completely different needs from high-functioning adults, who can speak, work, and self-advocate at meetings like this one.

And it's not a small group. Fully 50 percent of the autistic population also have intellectual disability, 20 percent are nonverbal, and as I already mentioned, up to 30 percent suffer from aggressive and self-injurious behaviors.

These symptoms are all highly correlated with each other, resulting in thousands of individuals who fit all three categories.

Second, investigate treatment options that target this profoundly disabled group. One promising area is the use of electroconvulsive therapy to treat the comorbid, affective and catatonic disorders that often drive aggression and self-injury.

My own son is living at home today and not in a highly restricted residential facility because of the remarkable stabilization he achieved through ECT, and he's not alone.

There are many cases in the psychiatric literature of young people with developmental delay and dangerous behaviors whose rages have been stopped by ECT, including, by the way, the young woman who blinded herself. Unfortunately for her, her parents found this treatment too late to save her sight.

Finally, expand both inpatient and outpatient psychiatric services to treat autistic individuals with dangerous behaviors, EASI foundation is working to establish a best practices guide for treating this population because right now, treatment is driven largely by the experience and philosophical orientation of whatever provider happens to be involved.

It's not uncommon for a psychologist to tell parents that aggression and self-injury can be resolved through behavior modification only, even if the research indicates that severe behaviors are the result of neuropsychiatric disturbances that require medical intervention, nor is it uncommon for child psychiatrists to reject ECT simply because they are unfamiliar with its use in this population.

These children are so complicated, with behaviors that are particularly resistant to much pharmacological treatment that a true team approach is needed, utilizing the expertise of providers of different disciplines. Unfortunately right now, there are only a couple of facilities in the entire country staffed with experienced psychiatrists, behavior specialists and ECT providers.

I'm sure you can imagine how frustrating and heartbreaking it is for parents who contact me to learn there are treatments that might help their children, but that just aren't available anywhere near them.

These children, teens and adults and their families are suffering every day. They're an underserved, isolated population that has been under-represented in the previous Strategic Plans, both in terms of research participation and in treatment needs.

I hope that the advocates at the table, when they lobby for Nothing About Us Without Us will remember that these kids are a part of the Us.

I will leave EASI Foundation brochures if anyone is interested in more information. Thank you so much for your time.

Dr. Insel: Thank you. And as I said, we'll come back to comments and discussion with the Committee later in the day. Because of time, we're going to move on quickly to Dena Gassner.

Dena Gassner: Good afternoon. My name is Dena Gassner. I am a licensed and UCEDD-trained social worker providing direct hand over hand systems navigation support to teens and adults with Asperger's Syndrome and PDD-NOS based out of Nashville, Tennessee for the last 6 years.

When I arrived in Tennessee, it was

presumed that there was no adult population of people with Asperger's in need of the services we provide.

Thank you for allowing me to take today to address two significant needs. First, I have grave concern that we're not engaging in sufficient longitudinal studies to explore the emotional and physical implications of a lifetime of disenfranchisement from community resources and supports.

In my professional experience, the later the diagnosis, the more likely it will be complicated with co-occurring mental illness or physical disability.

Many states deny services, as does Tennessee, via the below IQ standard, resulting in this segment of the community being without services until co-occurring mental health issues develop.

I, myself, was diagnosed through the back door of mental health. I was misdiagnosed for 10 years with bi-polar disorder. The treatment that I received for that incapacitated me for the first 15 years of my children's lives.

Many states, I'm sorry. Mental health providers are not properly prepared to address the unique needs presented by this unidentified part of the population.

Lastly, I'm also seeing increased incidence rate for physical issues such as scoliosis, fibromyalgia, lupus and other autoimmune issues in our unsupported adult population.

Our community must realize that their intellect is no remedy for these very disabling issues. Although at first blush, one would believe that the population I serve should be able to self-advocate, they are all very severely impacted by this condition. And without needed research that would move us from anecdotal to application, the implications of these denials are tremendous.

Secondly and primarily today, I would like to address the massive denial of services to women with autism spectrum conditions.

In my practice, the gender ratio is one to one, women to men. My colleagues in the nation who make an effort to find women on the autism spectrum to work with them are finding no more than a two to one differential in gender representation.

Despite statistics in other countries and other parts of the country that two to one is more accurate, we continue to operate under a gender bias that includes dependency on the male phenotype for the expression, Tony Attwood, of ASD.

Of the women I have served at my practice and in national training, I have not met a single woman who has not endured emotional, physical, and sexual abuse. Not one. We're talking hundreds and hundreds of women that I've come in contact with.

Some experienced rape but were unable to fully and accurately report the assault, stating things such as, quote, “it wasn't rape because he didn't hurt me.” When I asked her if she wanted to be with him, she said no. She didn't even realize the boundary had been crossed.

With astonishing frequency, these vulnerable women are subjected to relationships with partners who have abusive natures.

According to Brené Brown, a renowned expert on shame, of all marriages that end in divorce result in the women leaving with the children 90 percent of the time. Thus, the woman becomes the unsupported primary caregiver to children, many of whom will also experience autism.

According to what we know about the underemployment of persons with ASD, these mothers and their children are doomed to continue to live lives in poverty.

Many are re-victimized as they attempt, but often fail, to navigate the social politics required to ensure schools give their children what they need. Thus, the cycle of disenfranchisement continues.

Unplanned pregnancies, domestic violence and poverty occur at astronomical frequencies, and yet no one is noticing.

I can tell you this scenario is the rule rather than the exception. There is no research being done to substantiate what my colleagues and I can only report anecdotally.

But the damage is multi-generational. My mother also had autism. She married a man who beat her for 18 years. Then she married a sexual predator, who victimized me.

We really need to figure out how this works. While I respect the continued efforts toward employment and education, I can state with confidence that no one in my practice – I've seen 40 personal clients one on one aged 19 to 63 – is prepared to address either option.

We are not addressing autism in my practice. We're dealing with PTSD and undoing neglect and abuse. The focus on employment and education is moot without undoing the emotional trauma instilled upon us from late diagnosis.

Further, I ask that the IACC name a professional woman to its panel, a woman who has autism, who has endured such neglect, yet has risen to her highest level of personal achievement.

Ideally, the IACC would seek out a woman who has primarily, and in an ongoing manner, continued to seek professional development in her work at the grassroots level.

Also, it would be ideal if this woman has the experience of raising a child with autism. Further, I request that this woman's training stand comparably to the same manner of that as other professionals on the panel.

There are many, many of us out here who are social workers, psychologists, and service providers who are living with autism who have done our work, we've done our training, we've done the work and we need to be represented.

I do very much appreciate the work of the IACC and all the progress that's been made, but this is an untouched area that really needs to be addressed if we're going to save the next generation. Thank you.

Dr. Insel: Thank you. If you're listening in, I hope you'll put your phone on mute. The next speaker is Dawn Loughborough.

And I must say, I don't think we're going to have time for you to read this entire document. So if we only have 5 minutes, it's going to have to be abridged.

Dawn Loughborough: Hello. My name is Dawn Loughborough and I'm the mother of three great children, one with autism. I'm here today to convey physiological medical concerns and want to influence the standard of care for autism as a special patient population.

The autism community wants hospitals and clinicians, who are well educated and prepared for patients with autism. One could consider an autism care model similar to, like, St. Jude's approach to children's cancer, where the finest teams work together to facilitate clinical treatments and inform mainstream medical hospitals.

This approach would improve quality of care and potentially lower the costs by improving our children's long term health outcomes.

It would guide delivery of care regarding considerations for drug interactions, anesthesia selection and follow on care.

Regardless of whether you are agnostic about the cause of regressive autism or, like many parents, observe cascading vaccine-induced developmental regression. Quite often regressive autism manifests with massive inflammation, which alters multiple systems in the body including the immune system, digestion and the nervous system.

These children cannot detoxify well. They have sensitivities and sensory problems.

Without a special population standard of care, our children's symptoms are often overlooked as being part of the way it is for autism, resulting in a type of discrimination that's impeding the coordination of care.

Our children need the same medical investigation as any other population, and perhaps need more specific workups to pre-screen for life-saving pre-conditions that impact things like their anesthesia selection.

If an autistic child comes to the ER with abdominal pain, are they given the same medical workups to rule out concerns like appendicitis, or are they dismissed with a bottle of laxatives since they have autism?

The relevance here is that IACC exists to coordinate autism. Autistic children are physically ill and require accurate diagnosis and appropriate treatment and quality of care.

I also ask that you go back to the IOM to do the gen-zero studies and the health outcome studies. I saw a little boy 4 days ago on the news. He was banging his head left to right, completely bloody. And his parents have looked for medical interventions. They're doing pretty well. But this is kind of common in our population.

So here are some general concerns. One, the intake analysis, it really lacks the collection of medical and physiological data. So our medical intake diagnostics when you go to a hospital, specific to regressive autism are absent from intake at hospitals and clinics.

A child with autism, including Medicaid patients, should be screened just like any other patient population. But when physicians hear the child is autistic, many are discriminated against, and their physiology dismissed as behavior or assumption of that is how it is for autism.

Two, medical management of adverse events. Emergency room staff and pediatrician's offices need to be trained to recognize drug and vaccine reactions, so they may start interventions immediately to reduce the impact of adverse events.

Three, medical screening needs to be

developed. An example is that mitochondrial disorders are not rare, but rather a common issue with regressive autism. Our children should be screened for mitochondrial disorders.

Patients should be referred to the proper immunologist, if they need a gastrointestinal specialist, or a neurologist for screenings. This is just simply not happening.

Many of these screenings are not in place in clinical settings for our autism population, and children go under-diagnosed.

Seizures are under-diagnosed. Sixty percent of autistic patients have seizure disorder or abnormal brain activity, often affecting speech and movement and social disorders.

Many children do not have their seizures detected because they are not referred to a neurologist for an EEG to look at their brain activity.

Five, immune system and gastrointestinal problems are disregarded. Faulty immune systems and severe gastrointestinal symptoms occur in a large percentage of autistic children.

Sensitivities and allergies impact drug selection and anesthesia. Proper investigation of and diagnosis is rarely made, and the lack of investigation is nothing short of medical neglect for our children.

In other populations, endoscopy and colonoscopy are the standard that would be applied when they present with the same persistent, severe symptoms for bowel disease. When treated appropriately, we're finding drastic improvements, including behavioral.

Six, detox mechanisms are sub-par. Children with autism are not effective excretors. And seven, last, current infectious disease management is not specific to individual needs.

Policies are needed for extensive

coordination of care. I hope this shines some light on some of the very basic issues families are dealing with.

Since 1998, I've had parent mentoring conversations with these families, and this is our reality. We are everywhere. Thank you for the agency's time. I hope you include us in your strategies going forward.

Dr. Insel: Thank you. And again, I would ask people listening in to keep their phones on mute so we're not getting feedback. Jake Crosby?

Jake Crosby: Hello. My name is Jake Crosby, for those of you who don't know me, I'm an MPH candidate studying epidemiology at the GW School of Public Health and Health Services and a contributing editor to Age of Autism, daily web newspaper of the autism epidemic.

The views I'm about to express here are my own. In the previous months following my last public comment to IACC, my general opinion of this Committee has not changed.

It is merely a tool of the federal agency, the NIH, implicated in covering up the causal role vaccines play in the autism epidemic.

It uses this tool to distract and deflect away from that cause by taking the autism community down the garden path of what the real causes of autism could be.

This is abundantly clear in my conversations with several key federal members of IACC, particularly the NIH director, Dr. Francis Collins and the IACC chair, Dr. Tom Insel.

I asked Francis Collins if he thought it was wise that Marie McCormick, chair of the 2004 IOM report aimed at whitewashing the vaccine/autism link had made up her mind about the vaccine/autism connection before looking at any evidence for or against, when she said on January 12th, 2001, and I quote, we are not ever going to come down that it, autism, is a true side effect.

First, Dr. Collins told me he didn't

think she made up her mind, and then he changed his story to claim that he didn't think her statements had much of an impact.

Didn't have much of an impact? This is the chairwoman of the panel that produced the scientific con job held up as a scientific consensus that vaccines don't cause autism for the IOM, which Collins himself agreed has global influence.

He also admitted that if IOM is corrupt, then that would corrupt the whole scientific process, but he would not admit IOM is corrupt.

So the director of the NIH does not think coming to a preconceived, evidence-free conclusion is corrupt. If that is not corrupt to him, what would be?

When I asked him why I was thrown out of NIH and dubbed a stalker by vaccine industry spokesman Paul Offit, after I corrected his faulty reasoning behind claiming that all autism begins prenatally, Collins told me you must not have been very diplomatic in your approach.

Before that, I wrote a letter to his office inquiring about my removal, for which I received no response.

I wasn't any happier following my conversation with Tom Insel, even though he holds a tremendous conflict of interest with his brother having developed the vaccine, the mercury-based, neurotoxic preservative thimerosal, which plays a causal role in the autism epidemic.

His response was that this happened before I was born. Therefore, presumably it's not a concern.

Well, of course it happened before I was born, I was born at the beginning of the autism epidemic, so the development of any vaccine that contributed to triggering the epidemic would have had to have taken place before my birth.

Another person whose performance I'm totally unimpressed with is SafeMinds' Lyn Redwood, who keeps asking for the creation of the same worthless NIH bureaucracies.

She confirmed with me via email that they were basically her pet project, as opposed to anything that is broadly desired by the autism community.

SafeMinds is the same group that gutted the congressional autism hearing by changing the topic from being about a vaccine autism cover-up to one about the federal response on epidemic denials like Ari Ne'eman to show up and give testimony.

The federal IACC members at the congressional hearing whose performance I was appalled at were Allen Guttmacher and Coleen Boyle. They cited the IOM Report at the hearing in spite of the fact that it was nothing more than a preconceived scientific con job.

When asked why it relied heavily on the work of indicted fraudster Paul Thorsen, she responded that those were only two studies.

In fact, Thorsen and his colleagues are responsible for four of the nine studies IOM uses to say vaccines don't cause autism, nearly half of this so-called scientific consensus.

Moreover, in seven of the nine studies included in the IOM, the investigators found an association between vaccines and autism, but were suppressed from the reported results by the investigators, including Thorsen's studies.

Thorsen, himself, was aware autism was going down after thimerosal was removed, but decided not to publish this. I wonder why.

Coleen Boyle, similarly, is fully aware the manipulation that happened in the CDC's vaccine safety datalink study, having herself noted gross under-reporting since it included children as young as 6 months.

She asked what would happen if the youngest children were ages 18 months to 2 years, children still young enough for many cases to go missed, but where under-reporting would not be as blatant or as noticeable.

Yet, she will publically deny anything

is amiss, while testifying under oath before Congress. Her presence on this Committee should alone discredit it.

It never ceases to amaze me how proven and unsubstantiated this cover up is. Yet instead of rectifying it, the government keeps committing it in the form of a smoke and mirrors sideshow like the IACC. Thank you.

Dr. Insel: Thank you, Jake. We're going to go on to Megan O'Boyle and Geraldine Bliss. And again, with time pressing, we may need to hold to pretty close to 5 minutes. Thank you.

Megan O’Boyle: Good afternoon. Thank you for having me here. I'm reading a comment on behalf of Geraldine Bliss. She is unable to travel due to her son's epilepsy caused by Phelan-McDermid Syndrome.

And Phelan-McDermid Syndrome is a genetic cause of autism, or one of the many genetic causes of autism. I'm just going to read her words.

My name is Geraldine Bliss and I have a 14 year old son with autism caused by a partial deletion of the SHANK3 gene. I chair the research support committee of the Phelan-McDermid Syndrome Foundation.

This syndrome is caused by the deletion of the 22Q13 and mutation of the SHANK3 gene. This syndrome is highly associated with autism.

Fifty percent of the people with the syndrome meet strict criteria for autism and 80 percent fall on the spectrum. Approximately 1 percent of all cases of autism are caused by deletions of 22Q13 or SHANK3 mutations.

While that might not seem like very much, SHANK3 protein plays an important and central role in a synaptic structure, learning and memory in autism and it interacts with many other proteins critical to neurological functioning, and many of these proteins are also implicated in autism.

In the interest of time, I'm going to

skip down to some of her requests. In the Phelan-McDermid Syndrome community, we're very excited about a number of knockout mouse models.

These mice are some of the most important resources for hastening scientific research because it is impossible to look into the brains of people with autism to understand what is happening at a molecular level.

These mouse models allow scientists to study how genetic mutations cause molecular changes. My greatest hope is that my son's life will be improved by new drugs, not in a dozen years, but in a few years.

There are many projects that will need to be done, and they depend on well-validated models of systems that are widely available to the scientific community.

Unfortunately, there are systematic and institutional barriers that are slowing down the process of finding cures. These barriers are creating real problems for scientists who have failed to reproduce findings in many mouse models.

The inconsistencies stem from many different factors, but many of you on the IACC know that these problems are not insurmountable.

First, we need uniformly back-crossed lines to the role of genetic backgrounds and phenotypic variability will be minimized.

Second, we need more mouse models to be disseminated quickly to the scientific community. It's not okay for investigators to keep their mice for years and not make them available to other scientists, especially those that are funded by federal government. They're important national resources.

Third, we need programs that can ensure mouse models of autism undergo behavioral and electrophysiological phenotyping that is done in a standard fashion to minimize various sources.

Fourth, we need more scientists conducting replication studies. Industry representatives have repeatedly cautioned us about the needs for mouse findings to be reproduced before they are willing to make investigation of drug development. This is a real barrier.

Fifth, we need to make sure that the findings from the replication studies are published somewhere. We know that occasionally scientists do repeat the studies of their colleagues, but the findings, whether positive or negative, do not make it into the publications.

I urge you to look at the Simons Foundation and what they have begun and the initiatives that will address some of these systematic problems. They have plans to include only a few mouse models at first, and I'm extremely grateful that the SHANK3 mouse has been among the prioritized mice lines at Simons.

But the autism community will need more than just a few mouse models. As I've gotten more involved in science through my role in the syndrome, I've grown very concerned about what these barriers will mean for the autism community.

While it's important that we continue to have projects that are exploring new veins of research, we also need to make sure that cultivating the most promising areas of research in ways that will translate into effective therapeutics.

As you develop the strategies for our nation's research portfolio in 2013 and beyond, I urge you to consider how this systematically well validated mouse models widely available to the scientific community. Thank you for your time.

Dr. Insel: Thanks very much. That will complete the oral comments from the public. You also have written comments that have been submitted, and I know many of you looked at those before the meeting.

If you haven't, I encourage you to go through those. During the meeting, we'll have time, at this point it's scheduled for 4:15, to discuss both the oral and written comments from the public. And I want to go on with our agenda. We asked Deb Fein to come here from the University of Connecticut because of a recent paper of her work, which has gotten a considerable amount of attention in the press.

Deborah Fein's a clinical neuropsychologist who's been doing autism research for 35 years at Boston University School of Medicine and at the University of Connecticut.

She's currently the Board of Trustee's distinguished professor in the departments of psychology and pediatrics at the University of Connecticut.

She's investigated numerous areas in autism including biochemical abnormalities, brain waves, language and memory, cognitive skills, sensory abnormalities, outcome early detection and screening, and theoretical issues concerning diagnosis.

She's published many articles and

chapters, mostly on autism and is the co-author of a book for teachers, “Autism in Your Classroom” as well as the widely used screening tool, the M-CHAT.

She recently edited the “Neuropsychology of Autism” for Oxford Press. She served on the Board of Directors of the American Association for Clinical Neuropsychology, Secretary of the International Society for Autism Research, and is currently on the Scientific Advisory Board of Autism Speaks and Associate Editor of the APA *Journal of Neuropsychology*.

Deb, great to have you here. I don't want to steal any more of your time, but thanks so much for coming on short notice.

Dr. Fein: Thank you very much, Dr. Insel. I appreciate the invitation. I'm going to stay at the 35 years, I'm not getting more and more experienced. It's just staying with 35 years.

Okay, I'm going to just give you a couple of slides of background and then very briefly touch on two prior studies that kind of led up to the study that was published a couple of weeks ago, and then perhaps talk a little bit about future work that we hope to do.

So we published a review article. First author is Molly Helt in *Neuropsychology Review*, really looking at a review of all of the longitudinal studies.

We concluded that somewhere between 3 and 25 percent of individuals, who are followed over time no longer meet criteria for autism on follow up.

However, most individuals no longer meeting criteria still show significant impairment in either social or language functioning such as the studies of Joe Piven and Turner and Wendy Stone.

The study that everybody talks about was the initial study published by Lovaas in 1987, in which about half of a group, who received 40 hours of ABA, were then regularly – um, successfully completed regular first grade and had average or better scores on IQ tests.

There have been numerous attempts to replicate that over the years, and they generally report some children reaching this outcome, but except for a couple of studies, not as many as Lovaas originally claimed.

Peter Mundy pointed out that having an IQ in the normal range and functioning in a regular education classroom is possible, is consistent with high-functioning autism and doesn't, by itself, constitute losing the diagnosis.

But the purpose of our optimal outcome studies – Geri and I were talking about this over lunch – there's hardly a clinician, who hasn't reported that they have a number of children that they follow over time who have genuinely lost the diagnosis and really appear to be functioning in most ways – in terms of language and social functioning – indistinguishable from kids, who never were on the spectrum.

So what we wanted to do with these – what we're calling optimal outcome studies – is to really provide some firmer scientific basis for that claim.

So we wanted to document the phenomenon, that was really the first aim, in which children with a clear history of ASD no longer meet criteria for ASD and who have really social or language functioning that really is not consistent with a diagnosis of ASD.

Now we're not saying that these kids are completely indistinguishable from typical in all ways. We were interested in exploring any residual differences or difficulties that they had such as anxiety disorder or learning disabilities that either might shed light on some of the core deficits of autism, or might suggest that they still needed either extra help in school or psychiatric help.

So we were interested in what additional support they might need. And then the more difficult question is really to try to explore mechanisms of this outcome by trying to get some intervention data, which is at this point retrospective, and therefore is going to be hard to really have a great deal of confidence in, but also to collect structural and functional imaging to try to see if the structure of the brains of these kids is more like our group of high-functioning autism or more like the typically-developing control group.

And when they do tasks, language tasks, social cognitive tasks, what kind of activation are we seeing? So does it look more like normalization of function, more like compensation, or in some third way?

So two prior studies that I'm just going to mention really briefly, Sutera et al. In 2007, we followed 73 children diagnosed because they screened positive on the M-CHAT, and we followed them to age 4.

Eighteen percent had lost the diagnosis by age 4. And the purpose of that study was to look back at the age 2 data, which had been collected prospectively to see if there was anything striking that could have predicted this outcome.

The bottom line is that motor functioning was really the only strongly predictive variable. So we have, there's quite a few graphs in this paper, and they mostly look like this.

So these are the kids who stayed on the spectrum, and this is the number of *DSM-IV* symptoms that they had. These are the kids who were not found to be autistic at time 2 or 4.

And then these were the kids who lost the diagnosis. They were really indistinguishable at age 2, and then indistinguishable from the kids, who had never been on the spectrum by age 4. Vineland Communication data looked just the same, indistinguishable at age 2 from the kids who stayed on the spectrum. And then really functioning, 100 is average here, so really functioning quite in the average range.

The only variables we found that clearly didn't show this pattern were motor functioning, where the kids who moved off the spectrum, really had motor functioning on several measures, not just this one, that was quite average at time one.

The second study that I'll just briefly allude to was looking at head circumference. So we took these kids who had moved off the spectrum. We went back to their medical records and we got height, weight, and some other growth parameters from the medical records.

And we were thinking, well, if these kids really didn't have autism at age 2, or if they had some different type of autism at age 2, then perhaps they would not show the accelerated head circumference growth that most people have found in samples of autistic kids.

But that isn't what we found. So this is the CDC norm, so this would be a standard mean of zero, a Z score of zero. These are the local Connecticut controls.

So they showed a little bit of this pattern, but all very close to average. These were the kids who stayed on the spectrum, so stable autism. And you can see that they show the accelerated head circumference. And then the slowed head growth coming back toward average that many, many people have found.

And then these are the kids who moved off the spectrum. Now these two are not significantly different from each other despite how they look. But they certainly had at least as pronounced head circumference growth.

So what we concluded from that is that it's likely that these kids are biologically different in some way. But whatever is being indexed by the head circumference growth was not differentiating.

So the current study, we have funding from NIMH, and thanks to Lisa Gilotty, who is our program officer who was extremely helpful over the years in many ways.

The collaborators, Bob Schultz at CHOP, Mike Stevens at the Institute of Living in Hartford, Letty Naigles, Maryann Barton and Inge-Marie Eigsti at the University of Connecticut.

Recruitment, we had a lot of help from Lynn Brennan, Harriet Levin, and then the graduate students Mike Rosenthal, who is now in New York, Katherine Tyson, Eva Troyb, Alyssa Orinstein, and Molly Helt.

The inclusion criteria, all subjects had to be functioning in the normal range of cognitive functioning. So verbal, non-verbal and full scale IQ standard scores greater than 77, which is 1.5 standard deviations.

No major psychopathology like active psychotic disorder. No severe visual or hearing impairments that would preclude participation. No seizure disorder, fragile-X, or head trauma.

So all of the subjects in all three groups met those criteria. For our optimal outcome individuals, this is how we established inclusion for optimal outcome.

So they had a documented ASD diagnosis made by a physician or psychologist, who specialized in autism, meaning that 51 percent of their practice or more was autism before the age of 5.

They had to have an early language delay. No words by 18 months or no phrases by 24 months because we really wanted kids, who had significant demonstrable developmental disorder and not just, you know, some quirky personality that somebody might label as Asperger's. We really wanted kids with autism and with a developmental delay.

Then we took the report, the earliest comprehensive report that we had, we took out information about diagnosis. We took out the summary and recommendations because obviously recommendations, if you recommended 30 hours of ABA, you knew that the clinician thought that this was autism, so we took that out.

And we gave them to Dr. Barton, who is

the head of our clinic who is an expert in early diagnosis, mixed in with foil reports of kids who did not have autism and blacked out the same information.

And Dr. Barton identified several kids, who we had really wanted to include in the optimal outcome group, but she said this is not convincing of early autism, so we threw those out.

And all of the foils were correctly identified by her as not autistic. And then they didn't meet any current ASD criteria as per the ADOS and expert clinical judgment, which I can go into more if there are questions.

In addition, they had to have Vineland communication and socialization scores in the normal range, full inclusion in a regular education with no aide, and they could have special services, but not in the domain of social functioning because we wanted to see if some of them might have attention problems, reading problems, math problems.

So we didn't want to preclude them on the basis of having any of those problems. But they couldn't have lunch bunch, social skills training, anything for autism in particular.

For HFA, they had to meet criteria for ASD on the ADOS and according to best estimate clinical judgment.

And for typical development, no ASD at any point in their development by parent report, no first degree relative with an ASD diagnosis, and no current diagnostic criteria, either by ADOS or by clinical judgment and again, functioning on communication and socialization in the normal range.

So we collected a lot of data. A big neuropsych battery, including cognitive functioning, some measures of social functioning, executive functioning, language, academics, psychiatric functioning.

Then we collected as much history as we could, and we did structural and functional imaging. And then we had four experimental tasks to look at some cognitive functions, for which there are really no standardized tests.

So these are the kids, 44 high-functioning autism, 34 optimal outcome, 34 typical development. And you can see the sex ratios, the average age. The age range was 8 to 21.

We were going to stop at 18, and then I started getting calls from parents and individuals, I go to Brown University. I'm one of your kids. Can I be in the study?

And we really wanted to include those kids. So, well, they're not kids. So we went up to age 21. IQ, you see that they're well matched on non-verbal IQ, which that was our goal was to match them on non-verbal IQ.

The optimal outcome and typical kids were well matched on verbal IQ. The HFA group, still above average, but not as high as either of these groups, and not as high as their non-verbal IQ. So we co-varied verbal

IQ on all of our language measures.

So this is the ADOS totals, where if you add communication and social, I believe it's a cutoff of seven for spectrum and ten for autistic disorder. And you can see what they look like on communication.

These are the optimal outcome kids, and you can see that they are really very close to the typical development kids. A little bit higher here, but this difference is not at all significant. And you can see that they're not anywhere near the cutoff.

The social communication questionnaire, which is a 40-item questionnaire, that kind of mirrors the ADI, we used the lifetime version to try to get as good early history as we could in terms of severity of disorder.

And there was a difference here. Of course, the typical kids, very low. The cutoff here, for some age groups it's 15, for some age groups 11 seems to be better. But you can see the typical kids are very low.

The optimal outcome kids are well above

cutoff, but this difference is significant. So they had slightly but significantly milder parent report of early autism.

And on the ADI where you can break the three domains of autism apart, this is the HFA versus optimal outcome kids, there was a difference on socialization, where the optimal outcome kids had slightly milder, but significantly milder social symptoms.

But there was no difference in communication, no difference in repetitive behaviors. This was a surprise to me because clinically, kids with severe repetitive behaviors, at least, you know, a clinical observation and there's some literature on this, tend to have not as good outcome.

And if you talk to behavior therapists, it's not the social and sometimes not even the language symptoms that are hard to remediate with behavioral intervention, it's really the repetitive behaviors that can be really hard to remediate. So I was kind of surprised at that finding.

On the Vineland communication, there was no difference between the optimal outcome and typical kids. Now of course, the HFA kids were a little lower because we didn't require them to have above a 77.

On socialization, you can see that there's no difference between the optimal outcome and typical kids. And as you would expect, the kids who are still on the spectrum are lower.

Daily living, we had no inclusion criteria, so that could have freely varied all over the place. And the optimal outcome kids were a little bit higher, not significantly, than the typical kids on daily living, and the HFA kids were lower than both of those groups.

We also did Benton Face Recognition because face recognition is a very prominent symptom in autism, having problems with face recognition.

We presented some data on something else at IMFAR about 3 years ago, and we had somebody come up to our poster and say I'm so glad to see something that's not on face recognition. It's really become a very dominant and very important part of the field.

So this is a standardized test with face recognition. Zero would be average. You can see the optimal outcome kids are right at average.

These typical kids a little above average, but this is not different. And the high functioning autistic kids were about a half a standard deviation, on average, below, and lower than the other two groups.

Dr. Insel: Deb, just a second. I'll have to interrupt. Can we ask you to mute your phone? We're still getting a fair amount of interference.

(inaudible comments.)

Dr. Insel: No, there will be, or there could be. Whoever is joining us from the Committee but is not able to attend, we want them to be able to talk to us. How to mute?

Operator: Star 6 to mute.

Dr. Insel: Thank you.

Dr. Fein: So we have several other papers that are either in press, or under review, or about to be submitted. And I'll just give you a couple of highlights of those.

So we had Eva Troyb looked at academic skills and we looked at reading, decoding, passage comprehension, written expression, and math problem solving.

All three groups were in the average range. And the optimal outcome in typical kids had no differences.

The HFA group was a little lower, still within the average range, but significantly lower on reading comprehension and math problem solving, the math problem solving probably because these are word problems. So they require simultaneous mathematical processing and verbal comprehension processing.

I think one of the most interesting

questions that we're going to be looking at is psychiatric outcomes. And the most common comorbidities reported for autism in the literature in general are anxiety, OCD, tics, depression, ADHD, and oppositional defiant disorder. And these are quite common in autism.

We're still analyzing these data, so what I'm going to show you is just a little bit of data from 2 years ago from an IMFAR poster.

So this was when about half the sample was analyzed. So this is not yet published and we're going to be updating this within the next couple of months. And these are all above threshold.

There were additional kids, who had sub-thresholds, so there were a bunch of typical kids, who had phobias, but they didn't quite meet threshold on the case [inaudible comment.], and some ADHD symptoms and some tics. And probably some depression too, but none that reached threshold.

So what we're finding most of is – and these are percents not ‘N’s – the high-functioning kids with autism had some phobias, a lot of ADHD, which you're not supposed to diagnose but we did, and then some tics.

And the optimal outcome kids had bunches of specific phobias, ADHD, and some tics. We looked at tics in particular because Michele Zappella, who is an Italian psychiatrist, published a kind of similar series in 1999, in which he reported that early in development the kids that he called optimal outcome all had tics.

So he thinks that tics were early a very positive prognostic sign. We are finding tics in this group, but there seem to be more tics, if anything, in the HFA kids. I think the phobias are also very interesting, the nature of the phobias. So Dr. Barton, who's the head of our clinic, pointed out, when we started looking at what kinds of phobias, that the phobias that we're seeing in the high-functioning autism group and the optimal-outcome group could be interpreted as left over phobias from sensory sensitivities.

So they tended to be afraid of dogs barking, not getting bitten but barking, babies crying, things like that, that we didn't see in the typical kids.

When the typical kids had phobias they were snakes, and the forest, and the dark, and sort of more classic phobias. But again, we have to look at the entire sample.

Okay, so far what we can say is that this group, what we're calling the optimal-outcome group, showed no obvious social language or cognitive differences from the typical group.

The predictors of optimal outcome seem to be similar to the predictors of better outcome in general, higher IQ and better social functioning, which is higher cognitive ability when the kids are little, better motor functioning, and milder social symptoms.

As I mentioned, to my surprise, high rates of repetitive behavior don't seem to preclude this outcome. Whatever the biological difference is that's marking this group, it was not evident in the head circumference findings.

I think one thing is we required IQ scores, verbal and non-verbal, of 77 and above. But the IQs in the optimal-outcome group, which we then tried to match to the HFA group, were closer to one standard of deviation above average.

They were close to 115. And I'm wondering if that, having not just in the average range but really superior IQ, allows a further degree of compensation.

And then we're looking at residual deficits, or vulnerabilities, in the optimal-outcome group, which so far the most prominent ones seem to be anxiety and attention.

Okay, many, many open questions, so I've gotten a lot of media questions, and questions from parents. What percent of ASD children with good intervention could reach this outcome?

We really have no idea. One would need a large-scale epidemiological study with good intervention, however one defines that. From the smaller prospective study that we did, where we found 18 percent, and from looking at Piven's study, and Wendy Stone's study, and a bunch of other studies, it seems like 10 to 25 percent is in about the order of magnitude that we're talking about.

Is behavioral intervention necessary to produce this outcome? We have recollections from parents of intervention. I know it's going to be really difficult and messy to analyze.

The kids that I see clinically, because they're mostly from Massachusetts, Connecticut, New York, eastern Massachusetts, most of them get behavioral intervention because that's fairly readily available where we are.

We did get some kids from Canada. We did fly in some kids from other parts of the country, who are in the optimal-outcome group. So it's going to be very interesting to see if those tended to be the kids who got more behavioral intervention.

Do the children who can really lose the diagnosis have a distinctive set of genetic or environmental etiologies? We have no idea.

And then are these kids and young adults arriving at their overt behavior through different means?

So I was mentioning to Mr. Robison at lunch that my model for this is Guin Eden and other people's dyslexia work, where they do intensive remediation.

They normalize the reading and then they look at what brain systems, what's the degree of activation, and which brain systems are being used by the formerly dyslexic individuals. And they're finding sort of a combination of normalization and compensation. I'd be surprised if we get anything that clean. I'd be really surprised. But we're certainly going to look at it.

There are many mechanisms. It's possible to speculate, this is sheer speculation, about how one could lose the symptoms to this extent. And these are really just speculative thoughts.

Mundy and Crosson have a very nice paper in which they speculate that there's a neurologically-based deficit in social orienting, and that with intense behavioral intervention you prevent that from the cascade of other neurological and behavioral problems that may result.

Geri Dawson has a lovely paper about pairing social contact with the primary reinforcers, resulting in the social contact developing secondary reinforcing value.

And then I think what we have to figure out is how does this connection become autonomous. Because normally if you do an operant conditioning paradigm, and then you cut that connection, you get extinction.

So what's allowing this to get internalized? It may be that there's successful suppression of interfering behaviors, which allows the child to really, this is Marcel Kinsbourne's point of view, and I really think that I agree with it to a large extent, which is that the crucial element in successful therapy is to draw attention from inside, from mental processing, out into the environment.

And that's probably not sufficient, but probably necessary, and then possibly teaching alternative routes to the same skills.

So there are many questions, obviously, that this could lead to. One is that we have a pretty non-diverse sample, geographically and socioeconomically, and ethnically.

Another is what happens when these people get into their mid-20s, 30, what does their outcome look like.

A really important but probably very difficult question is: are there biological differences between the group that, even though very high-functioning, still have persisting autism, and the optimal-outcome individuals.

And then long term follow-up, we have a large sample of kids at age 2. If we had enough of these kids and we followed them up to age 8 or 10, could we get a better estimate of the number, who can really reach this outcome?

And then another, I think, very interesting thing would be to really follow them as they emerge from their symptoms to see is it the language that gets remediated first. Does the repetitive behavior get suppressed first? What is actually the developmental pathways? And then to try to get some better intervention history.

The last thing is that there's been a lot of great coverage in the last 2 weeks in the media, but some not so great coverage. And I think it was the BBC initially said children are found to outgrow autism, which of course I never said. And then it was picked up by many other outlets. I've never seen a child grow out of autism without intervention. Maybe it's possible, but I have never seen it. And certainly the children in our study did not grow out of it without intervention.

And therefore, these findings are not an argument for less early detection and less intervention, but if anything for more. Okay, thank you.

Dr. Insel: Thank you, that's a really great rundown on a body of work. I know there's a lot of interest here. And we'll start with Scott.

Mr. Robertson: So I think it's interesting findings in the work. The word compensation was used in your presentation at one point.

And I would have concern with there being equating between, a parallel between not showing up and showing the traits because of compensation, or compensatory strategies, adaptation, and establishing that someone is definitively non-autistic anymore.

And I say that because I have known many autistic adults, who are definitively still definitely autistic, out of the laboratory setting, where a lot of these tests are being done, out in the communities, et cetera, where you can see a wide variety of more social communication and interactions. You see a lot more challenges. And many autistic adults have often learned compensations for things like eye contact, et cetera, that are done on the ADOS.

Myself and many colleagues have been assessed on the ADOS and may not show up as readily available on the ADOS as autistic, because we've compensated for things like eye contact. We can make reciprocal conversations.

But guess what, we still have challenges out there in the community, out in life, in executive functioning, and social communication, et cetera.

Sometimes it's more subtle, things that may not show up as well in the instruments that were mentioned here in the study.

But I have really major concerns about grouping individuals, who have compensated for challenges, who show up for instance as autistic on the ADI, the print interview on the developmental history, but grouping them into this optimal-outcome group as separate from the autism spectrum, when these folks may just have learned compensation strategies that have helped them to adapt and to live in life and may mask a lot of the traits, and may, as many folks would say, "pass as normal."

You would see them on the street. You would not necessarily know they're autistic. But be around them extensively for many days in a row, many hours, and you would begin to see a lot more subtle things that may not show up on these instruments.

So I think with the future research to be thinking about some of these things, how there may be mitigating factors on compensation and adaptation that may affect some of this as folks develop and age through adolescence into adult life, and compensate for a lot of their difficulties, particularly sometimes folks, who cognitively sometimes apply cognitively different strategies they've learned to logically think through things like social communication challenges.

Dr. Fein: No, I think that's an excellent point. And so we tried to address it to some extent by getting information about their social functioning in school.

We had a lot of parent report and some self-report on that. We have Vineland, which really asks about how the person is functioning in the community.

But I agree with you, absolutely. And one of the reviewers of the paper made a very good point, which we acknowledged in the paper, which is to really be more confident you'd have to do a school observation where you really see the kid running around on the playground, interacting with peers. And I think that would be an excellent thing to do.

Dr. Insel: John?

Mr. Robison: With all due respect to the title of the study, optimal outcomes, I guess I would like to raise a question about how accurate that really is.

Because I know that the scoring of the ADOS test, as much as we want it to be impartial, is significantly influenced by the mindset of the people doing the tests.

You said just there, Scott, that you might not be scored as high on the test, as it were, because you've learned mannerisms. But let me say as a counter point to that, that both Temple Grandin and I are considerably older than you. And we've been subjected to these ADOS tests over a number of years.

And with both her and I, on a couple of occasions, we've been scored by grad students, didn't know who we were, didn't know anything. And the score changes quite a bit in context.

And I would suggest that if, rather than look at these kids in this test, you sent those kids to some new psychologist and you said this child is failing 11th grade, and would you evaluate them for autism and you evaluate them with only that as the context. I guess I question whether they would truly not be autistic because we are not, even though we seemingly have an optimal outcome. The next point I'd like to make is that the use of the term ‘optimal outcome,’ well, I understand what the authors meant by using it. It's not an optimal outcome.

The fact is an optimal outcome in American society is a person, who lives independently, gets a job, supports himself, and has a family. That's a damn optimal outcome, not losing a diagnostic report on a piece of paper.

(Applause)

Mr. Robison: And so what we – and I was criticized for making this suggestion before

– but I'm going to make it again. I think if we want to study optimal outcome, what we ought to do is find the successful geeks in this world and study them.

Find those people who are, whatever you want to call it, high-functioning autistic people, who outgrew diagnoses, whatever you want to say, they are people who score within the range, like say Temple and I, on an ADOS test. But they are able to do those things. And then look at the population, which is very, very large, of people who have lost their diagnoses, they score well on all other tests, but they don't have jobs, they don't have wives, they don't have kids, they don't have any of that stuff. What sets us apart? And that is a very, very troubling thing to me. Because I see studies like this and they talk about these wonderful results. And it's not, by God, delivered in real life. I look at the studies and then I look at the populations. And I see these people. And they're smarter than me, and they do better than me on all these tests. And they don't have any diagnosis. And they're on disability. And it's wrong that we don't understand that.

And to me, as encouraging as the information that Dr. Fein presented to us today, it just tells me how vitally important it is for us to study some people in middle age, with a judgment that we would all agree with, of what is an optimal outcome, and try and figure out how they got there.

And I'd compare that to the Utah study we've done, Autism Speaks. And the Government has both funded that, looking at the 30-year study there, the University of Utah. We need to do something like that, but looking at people much higher on the functioning scale.

Dr. Fein: So I don't think there'd be any disagreement that what I want for the kids, what the parents want for the kids, is to be functional, happy, have relationships, have work, be economically self-sufficient. And the kids that w, the young adults that we're describing, are one kind of optimal outcome.

If somebody has autism, persistent autism, and is happy and productive, and has relationships, and is economically self-sufficient, of course that's another excellent outcome. You couldn't ask for better than that.

But this is one group that we were trying to document. And also we didn't assume that because they had scores on these tests, and had cognitive functioning, that they were well-adjusted psychiatrically, and that they weren't anxious and depressed.

So we're collecting those data. But I can tell you that there was virtually no depression, for what that's worth, in this group.

And they are not yet old enough to know how they're going to make it in the adult world. College age is the oldest that they are right now.

Mr. Robison: I'm afraid that I might

have made you feel like you're defending the study, or whatever. And I didn't mean that all. I didn't mean to criticize what you did.

Because I think you did a study that's legitimate, and it provides good hope to people. It's a very hopeful study. I just wanted to point out that optimal outcome really does mean something different to most of the world.

And I think what you've done is a first step. And we need to take a population like that and follow them for 20 years. But we need to find a similar group, who's already out there, so we don't have to wait 20 years for the data, and study them too.

I appreciate what you've done. And I didn't mean in any way to make you feel as if I was criticizing it.

Dr. Fein: No, I didn't, thank you. I was really agreeing with your major point about what constitutes a good outcome.

Dr. Insel: So we're going to take a few other comments. Why don't we start at this end and we'll work our way down. Lyn?

Ms. Redwood: Dr. Fein, thank you for this great presentation. I just had a question. I know a lot of families also use alternative and complementary medicine, it's a large percentage, something like 60 or 80 percent, along with behavioral therapies.

Is there any way to tease out what might be a recipe for getting this optimal outcome? You had future directions. I think it would be interesting to go back and look at all the therapies utilized, and to see if there's a way we could provide a little bit more guidance on treatment in terms of how to get these optimal outcomes.

Dr. Fein: Yes, that would be wonderful. We have records from the parents of every intervention, including biomedical interventions and other things like that. And we will certainly publish whatever we find.

The problem, as you know very well, is that this is not a prospective study. So we're relying on parent recollection if they're 21 years old and they didn't have any more treatment after 6.

I just think those data are going to be messy. But we will certainly publish whatever we find. And we did collect those data.

Dr. Insel: Jan?

Ms. Redwood: Thank you.

Ms. Crandy: Mine was kind of in line with hers. I want to applaud you for this study, because parents do want to know that it's possible.

On the intervention, did you also track the intensity? Are you asking for that? Because that'd be interesting to see the levels.

Dr. Fein: We are. We have intensity of intervention. But again, you know, it's recollection. And as I'm sure you know, the quality is probably at least as important as the quantity.

And even the quantity data is probably not going to be really very, very reliable. And the quality is going to be even harder to judge at a distance. But yes, we did collect intensity.

Dr. Insel: Idil and then Alison. And then we'll have to move on.

Ms. Abdull: Hi, once again, thank you also from me for doing this study. And if I can just sort of comment to what John said, that optimal outcome is different, right.

So for the real world, I would like my brothers to go to college, get a job, get married, and don't mooch off family. That's optimal.

But when you have a child with autism that is non-verbal, or is doing some of the things that the other Mom had said, optimal outcome is to be like you, to have the ability to communicate, to make your needs want, to be able to regulate whatever sensory or eye contact so that you can function.

To us that's optimal outcome. So it's sort of subjective. So I thank you. You give us hope. I thank you very much.

My question was somewhat similar to what

Jan and Lyn have said. Do you know the behavior? Do they all get ABA? Do they get the developmental, like Floortime and RDI, if we know the differences of the behavior therapy or what kind of therapies they got?

And then also, finally my last question, the diversity part, could you at the end tell us how many were diverse, from what ethnicities?

And just as a comment, I always hear increased diversity. So maybe next time, Dr. Fein, you can make it so that you outreach to children of color, you know what I mean, rather than at the end saying we needed to. I think we should hear ‘we have done it.’

Dr. Fein: Yes, absolutely. So I agree with you completely about an optimal outcome for one child is not going to be the same as an optimal outcome for another.

And the question about intervention, so we're collecting it. The majority of the kids, we started just trying to find local kids, who could drive for the MRI and so on.

Connecticut happens to be more Caucasian, I think, than any other state.

Ms. Abdull: Oh, I don't know about that, try Minnesota.

Dr. Fein: Yes, well, it's pretty close, if it's not Number 1. And then we were getting some of these kids through therapists, who delivered the very intensive intervention, who had kids who graduated from the program. So the way we ascertained the sample, I think, immediately put a bias. And really we were trying to find these kids. And it really took us 5 years to find all these kids, and collect all the data, and to analyze it.

So we will have to use different ascertainment methods next time to get a more diverse sample.

Dr. Insel: Thanks, last comment, Alison? And then, okay, Anshu, we'll have two more. But we've got to move on after that. I'm being too soft today.

Ms. Singer: Well, I'll yield my time.

Because I was going to make the same point about optimal outcome being very much dependent on your starting point.

Dr. Insel: Anshu?

Dr. Batra: My comment was thank you, first of all, for giving us families hope that there is a light at the end of the tunnel for some of us.

And again, I think this really describes a sub-type, an endo-phenotype, which again is exciting.

Two specific questions, one was what motor markers did you use? You said the motor tasks were prognostic.

Dr. Fein: Yes, so this was when they were 2, it was Vineland motor, Vineland gross motor, and Mullen early scales of learning.

Dr. Batra: Mullens was used as well, okay. And then secondly, what in the four experimental tests you used for data collection, the tone discrimination, how did you use that?

Dr. Fein: Yes, so it was an auditory

discrimination test easy, medium, and hard discrimination. And Doctor Eigsti is analyzing the data.

We did find that the high-functioning autistic kids did have better perceptual discrimination. And then we're looking at the relationship of current discrimination to early emergence of first words and phrases, which is finding a relationship.

Better auditory discrimination had later onset of words and phrases, I think in both the optimal outcome and the HFA groups.

Dr. Batra: Okay, thank you.

Dr. Insel: Thanks so much for coming. I had one last comment.

Dr. Fein: Can I say –

Dr. Insel: Yes.

Dr. Fein: – 10 seconds more to the question Alison didn't ask, which is that I've been seeing kids for 35 years, because I'm sticking with 35.

And I see them again after a year, or 6 months, or 2 years, 3 months. I cannot predict from the severity of the delay, or the behavior, when I see them.

They have to be in good intervention for a year or two. Then I can predict. But it's not exactly how they look when you first see them. I think that has very little predictive value, because I'm constantly surprised.

Dr. Insel: That's really important. I think that message, which we heard a little bit about 2 or 3 years ago at another IACC meeting, is one that we have to keep reminding all of ourselves about. That there's nothing in the behavioral phenotype that allows you to say something about prognosis, which is surprising. But it's the reality that we're faced with.

We know this is really heterogeneous, but we're not going to get the heterogeneity untangled by just observation. Deb, thanks so much for coming. This is really helpful.

(Applause)

Dr. Insel: Well, we are behind schedule. But I wanted to make sure we plunge into this next conversation quickly on the Study of Health Outcomes in Children with Autism and their Families.

This was a project I think you heard about before at an earlier phase. And it's going to be presented to us today by Dr. Anjali Jain, who's a senior researcher and managing consultant at the Lewin Group in Falls Church. She asked me not to spend any time on her bio, except I should say she's –

Dr. Jain: I haven't done 35 years of autism research.

Dr. Insel: – she hasn't done 35, right. But Dr. Jain is a pediatrician, who has been involved with lots of issues related to disabilities.

She served as the director of advocacy for the LEND Program at Children's National Medical Center, as well as authored narrative articles related to the care and healthcare of her daughter with developmental disabilities. So she's somebody who's well positioned to do this.

We've also asked Craig Newschaffer to join us. He's, I hope, joining by phone. Craig, are you there?

Dr. Jain: Yes, he wasn't able to attend at the last minute. But, Susan, is he on the phone?

Dr. Daniels: He said he was going to be on the phone. Craig, are you there?

Dr. Insel: Are you on mute and not communicating, or are you just not there?

Dr. Daniels: I did give him the speaking line.

Dr. Jain: Maybe he'll chime in. I don't know –

Dr. Daniels: He might join us a little later in the presentation.

Dr. Newschaffer: I am on the phone.

Dr. Insel: Welcome. And I –

Dr. Newschaffer: You can hear me? Okay, would be great.

Dr. Insel: And you need no introduction, because you know this group pretty well, and I think they know you. So let's plunge right into this. And thanks so much to both of you for –

Dr. Jain: And thank you to the Committee for inviting us here to present, and certainly to NIH and Ann Wagner and Frank for their support and guidance along the way.

So first I'll present a project overview and then some key findings, and leave time for questions, hopefully. Because there's so much information that's part of the study, it's going to be at a pretty high level and pretty broad, just to give you a flavor of what we did, our approach, as well as some of the things we found.

And we're happy to discuss questions in more detail later, as well as electronically, if people are interested in that.

So this project was a true collaboration between us at the Lewin Group, which is a health and human services policy consulting organization just inside the Beltway, along with OptumHealth, which provides behavioral healthcare and research, and OptumInsight, both of which are our sister companies and part of the United Health Group, as well as Craig Newschaffer and his team at Drexel University.

So our objective overall was to use existing administrative data to further our understanding about autism spectrum disorders, including diagnosis, risk factors, and health outcomes and healthcare use among children with autism, as well as among their family members, by which we mean siblings and parents.

The deliverables for this project are five reports that are final and complete, but are not yet disseminated. And those are pending the results of the manuscript we've submitted for publication.

And there's one manuscript that's in press at *Autism*, and two that are under review. And I'll talk a little bit about those later. We also are submitting a data set to NDAR for use by future researchers. That's almost finished.

So just because I know that there's a variety of levels of experience in the room, I'm just going to briefly describe what are administrative claims data.

So this is data submitted by providers, sometimes by patients and families, to health insurance companies. So it includes information for billing purposes, primarily. So that means there is an ability to identify doctors, hospitals, services that are provided, as well as diagnosis codes.

So procedures and services that are not well covered by the health insurance plan in particular, or more generally, are not included. So things like ABA or speech therapy services that are offered at schools, for instance, would not be well represented in this data.

It also typically does not include any, or very much, of the clinical information associated with each individual child, so just some of those things to keep in mind.

So for our study in particular, we

looked at the time period between 2001, 2009. And as I said, we had diagnosis codes, procedure codes, some provider characteristics, and cost and payments in terms of healthcare service use.

We also had very good pharmacy information, including prescriptions that were filled. We can't be completely certain that they were taken, necessarily, but that they were actually filled by the pharmacy, including dosages, length of the script in days, and unfortunately with not always good information on the prescriber of that medication.

We also had similar codes and procedures for mental and behavioral health. And in this particular insurance plan, autism was covered, at least partially.

We didn't have direct source of sociodemographic information. But we were able to link to an external marketing database that has been validated. And at that level we were able to derive income and race for about half of the sample, not for all.

And because of health plan linkage, we were also able to link to family members that are on the same health plan as the children with autism, as well as the children without.

And we know that the data set is pretty geographically-diverse across the U.S., although we had to give up a lot of granularity about geographic information.

So we only have the four major census tracts in terms of the location of services for the children in the data set.

So just looking at the sample over this 9 to 10 year period, we ended up with over 46,000 children who had at least one diagnosis claim with an autism spectrum disorder. So I'm going to use autism and autism spectrum disorders fairly interchangeably in this talk.

And then we also pulled a comparison group. And I think this is one of the unique things of our study, is that we were able to have a very large comparison group.

So we pulled three children from the general population, but without an autism claim, for every child with autism. And then we grabbed all their parents and all their siblings, in fact all their household members. And we came up with algorithms to identify who was the father, who was the mother, and who was a sibling.

So the race and ethnicity information was not available for about half of the kids, or a little bit less than that actually. But when it was available, about 75 percent of the sample was white, which is similar to other privately-insured data sets.

Okay, so the first part of our study was to try to make sure that the children with the claim for autism actually had autism, or some evidence, or clinical evidence of having an autism spectrum disorder, and not that it was just a mistaken diagnostic label.

So we did a smaller chart study with over 400 charts. And we looked at whether or not there was evidence of autism in that child's chart.

Now this chart was only one chart from one provider during the period of enrollment. So we didn't have the child's entire medical record.

So if we had that, these values might be even higher. But we found that if a child had one claim with an autism diagnosis, in any position, meaning it could be the primary diagnosis or second, on down, that the positive predictive value was 74.2 percent that there was evidence of autism in the medical chart.

And if a child had two or more claims, the PPV increased to about 87 percent. So at that point, we decided that for the rest of the analysis we wanted to make darn sure that the kids had autism.

And so we limited it to the number that had two claims or more, which still left us with over 33,000 children with two or more autism claims.

Okay, so this is just descriptive percentages and some unadjusted odds ratios of some of these very broad groups of health outcomes.

I'll see if I can use the pointer. Well, it's probably not necessary. So as you can see with the neurologic disorders, and the mental health conditions, there's much higher percentages among the children with autism compared to the other children.

But if you look overall, pretty much every group of conditions has a significantly higher percentage in the children with autism compared to the others.

And then some of the ones that were a little bit more surprising, I think, were the things like infectious diseases, as well as injuries potentially that had higher percentages with those conditions compared to the comparison group.

We also found, if you look at the gastrointestinal and nutritional conditions, this was much higher as well. And if you compare this to the literature, I have to say that we took a broader view as to what constitutes a gastrointestinal condition.

So we included things like simple constipation and diarrhea and things like that, in both groups of course.

So if you're comparing some of these estimates to what's out there in the literature, that's some of the reasons for the discrepancies.

So we also looked at siblings of children with autism, compared to siblings of the control group. And this is a different scale than the previous. So just keep that in mind.

But still, for siblings as well, they had a much higher rate of pretty much everything compared to siblings of children without autism.

This has not been well studied, so it's hard to compare it to literature. But we're not, of course, assuming any sort of etiologic mechanism, but likely that there is shared environment as well as biology.

And for parents, we looked at a few

things in particular. And this is a broad definition of what we called stress-related conditions, including mental health disorders, as well as some things that would be included, like sleep disorders, and substance abuse.

We also included what we called physical conditions with stress-related triggers. And those are things that are like hypertension and/or asthma that might be exacerbated by stress.

And just keep in mind that all of these have to do with a clinical visit of some kind. So these are the level where they actually required some form of care.

So then we took a few what we call deeper dive questions, where we did a more detailed multivariate analysis, unlike the previous estimates I showed you where we did not control for things like gender, and race, as well as enrollment time.

These following questions I'm going to present now, we do control for gender, race, income – when it was available –as well as selected co-occurring conditions, which makes a big difference in how some of these play out.

So for gastrointestinal disorders, I know there's been a lot of interest in this. And one more point is that we, as part of our study from the get go, we had convened an external advisory panel, which included many people here, as well as individuals with autism, researchers, clinicians, parents.

And so we really took a lot of their views as to what were some of the priority questions that we wanted to answer, as well as we could answer reasonably well, that would move the field.

So some of these choices have to do with a really collaborative view of what we should look at. Because as you'll be able to see, there's a million questions out there that we could help to answer, I think.

So one of the first ones was gastrointestinal conditions and understanding the major impact this has on quality of life. And so we wanted to compare children with autism to those without in terms of GI conditions overall, as well as to try to get an understanding of if that changed relative to a child's initial diagnosis of autism. So we found that children with autism were much more likely to have GI conditions and symptoms. And that the odds of having one went up after diagnosis, compared to before.

For stress-related conditions, perhaps not surprising to anyone here, is that parents also had higher odds of having stress-related conditions compared to parents without.

Actually both groups were kind of high in terms of having stress-related conditions. I don't know if we want to go back, so something like 40 versus 50-something percent.

And that too went up after diagnosis of autism. We weren't sure that that's what we would find. We didn't know if finally getting a diagnosis would be relief, or potentially an exacerbation. So we can hypothesize perhaps it's the latter.

In terms of healthcare use, now we do have a lot more detailed information here that'll come out in the report. But just overall, children with autism, as David Mandell's work and others have confirmed, have a much higher use of healthcare.

And so we found that they had a comparison of 21 total healthcare visits per year compared to 5 visits for children without autism.

They also had more behavioral health visits, which I think is a good thing, 11 compared to 1, and on average had more medication use with 3 medications annually compared to 2 unique medications for children without ASD. This is all medications, including things like antibiotics, et cetera.

One of the more detailed analyses we did is to try to understand whether or not having a diagnosis of autism in an older sibling resulted in change in the vaccination status of a younger sibling.

So we compared MMR vaccination, just the first one from the 12- to 24-month period, between children with and without autism, as well as between children with autism and their younger siblings, and comparison children and their younger siblings, as well as the younger siblings of children with autism compared to the younger siblings of children without autism.

So we did indeed find that younger siblings of children with autism were less likely to be vaccinated with the first MMR than their older siblings who had autism.

We also found that they were less likely to be vaccinated than the younger siblings of children without ASD.

And we did, considering that this was sort of a 10-year time span during which vaccination rates had some secular trends going on as well, we found that so these kind of held up to those secular trends as well. I think vaccination rates actually went up overall in that time period.

So these are the topics of the two papers that are under review for publication. One is an examination of some of the risk factors for injury among children with autism spectrum disorders.

And the other is around the use of psychotropic, or psychiatric, medications, as well as studying the extent of polypharmacy, or the simultaneous use of psychiatric medications in children with ASD.

So I couldn't put this on the slides, but I'll tell you overall what we found. So overall we found that after controlling for co-occurring conditions, children with autism had a lower rate of injuries than children without.

In the unadjusted data, they had a higher rate. And this difference was also very age dependent, so children 0 to 5 years old still had a higher rate of injuries compared to children without autism.

But that completely was neutralized during the middle school years. And then they actually had a lower rate of injuries in adolescents compared to adolescents without autism.

In terms of psychiatric medication use, and again I'm breezing through this, so I'm happy to take questions afterwards. We found that approximately 35 percent of the kids with autism had multi-class – so had psychiatric medicines from more than one class – polypharmacy.

So they were using more than one medicine at the same time. And I believe it was something like 65 percent were using psychiatric medications at all, something like that, around 60 percent were using psychiatric medications at any time.

The odds of receiving a psychiatric medication, as well as polypharmacy, were higher for kids, who had seizures, ADD, bipolar, anxiety, or those that had seen a psychiatrist.

So the last part was to really try to explore the data as much more of a feasibility study than an attempt to get results, but to assess the extent to which claims data could be useful to examine risk factors for autism – early-life risk factors, maternal risk factors during pregnancy and prior to conception, considering the ones that would be apparent in claims, paternal risk factors prior to conception.

And so we included things like pre-term birth, chronic maternal health conditions, infertility treatment, anesthesia use, early immunizations, and the like.

So for this part of the study we estimated sample size to the extent that we could identify children, who later developed autism, as well as the comparison group, with their mothers, with their biologic mothers, as well as their fathers, who were in the data set prior to conception.

I included these slides just to give you a sense of how quickly the numbers can kind of go down.

Even though we started with 33,000 children, once you sort of limit those to the ones that have autism – which they had to have some period of time in the data set to appear with a diagnosis, which was often quite late – but then they still have to be enrolled at birth, and their mother had to be enrolled prior to that child's birth, and then their father had to be enrolled prior to that child's conception – the numbers do get quite small, but they're not insignificant.

Okay, so obviously one of the sort of very intoxicating strengths of this kind of study is the really large numbers we have. And it's been a wonderful set of data and individuals to work with.

And we do have a huge data set that I think represents such heterogeneity that really makes it have great potential for all kinds of questions, limited to what claims are good for, of course.

So anyway, one of our strengths is the

size, for sure, and that our data span a 10-year period. Of course, not many of those children were present during the entire 10 years.

But if we looked at individual children with autism, they averaged about almost a 4-year continuous enrollment period.

So that's still quite a lot of longitudinal data for these kids, and the ability to link to their family members. And examining the impact of autism on the entire family was, I think, a really fantastic value for this kind of study.

Some of our limitations are, again, knowing that these are for payment purposes, so it's only really as good as whoever is making that diagnosis claim when they're seeing the child.

And so it's subject to all of those constraints and limitations. So things that are not well reported or documented in claims, like obesity, for instance, are not going to be well captured in our data.

One of the really significant biases that we struggled with was an inability to really get a sense of how severe someone's autism was. Both intellectual disability and mental retardation – as well as non-verbal status – were highly under-reported. I think mental retardation was in about 2 percent of the kids. So we know it's not well captured.

We also thought that surveillance bias may have impacted our results. And sure enough, the children in the autism sample and their families had longer enrollments on average than the children without.

However, when we did do some analysis to control for preventive health visits to get a sense of who was the healthcare user in general, versus not, we did not find that that altered our findings very much at all. So, questions?

Dr. Insel: Thanks very, very much. Let me see if Craig has, before we start on questions, has additional comments to add.

Dr. Jain: Craig?

Dr. Newschaffer: Yes, I'm not going to take time with amplifying about it. I'll only say that the data set – the range of analyses – were completed was extraordinarily extensive.

And there's a number of other interesting findings, the ones that Anjali didn't have time to highlight. And I think that when the reports come out they will be of interest to a variety of folks around the table.

Dr. Insel: And speaking of that, is there anyone around the table who was on the panel on this, on the group? So Geri, you were part of it.

Dr. Jain: Geri, Alison, David –

Dr. Insel: David, okay. So we've got a lot of people who've been involved here. I saw lots of hands go up. We'll start here with John and go around.

Mr. Robison: I would thank you for a very interesting presentation there.

Dr. Jain: Thank you.

Mr. Robison: One question that I would have, looking at the slides, one certainly takes away the impression that the autistic population is generally sicklier, by every measure.

Dr. Jain: Yes.

Mr. Robison: And I wonder, since this is insurance health data, does it extend far enough out into the life span that one could predict mortality risk and differences for the autistic versus non-autistic populations? You would think that there would be a significant one, based on what you showed us.

Dr. Jain: Yes, I think that hypothetically the potential is certainly there. And we included everyone up to age 20 in this data set.

I think the problem would come in following one individual over the entire life span, because they're likely to change insurance plans, for one, but also –

Mr. Robison: But couldn't data be extracted for older people?

Dr. Jain: Sure, yes, absolutely. I know at the first EAC meeting – our external advisory committee – there's a lot of interest in using some of this data to understand autism in adults.

Dr. Newschaffer: Can I just, can I talk to you just real quick, John. Just in terms of going for the general conclusion that there's overall differences in general health status, the specter of surveillance bias is a real one.

It's very difficult to control for in an observational study like this. And while we did do some things, Anjali mentioned trying to adjust for the numbers of preventive care use, well, when we could we tried to adjust for length of enrollment when some of the kids for example in the ASD group tended to be in longer.

That would give them a longer time for another diagnosis to show up in the claims. We tried to make those adjustments. But they're very, they're not a perfect way of controlling for this sort of surveillance effect.

And from the health services research literature, we know that individuals with any chronic condition are going to be more likely to have an opportunity to be diagnosed with others. So we need to interpret those results with a fair measure of caution.

Mr. Robison: Well, even with that, it sure does suggest to me that we should be making more use of this database that you've shown us. And we should, as quickly as we can, evaluate the risks for older people.

Dr. Newschaffer: I totally agree.

Dr. Insel: Noah?

Mr. Britton: I was just wondering, were there any measures that you calculated that aren't reprinted here where the odds ratios were negative.

Dr. Jain: Not that I recall.

Mr. Britton: Okay, that's all.

Dr. Insel: Donna?

Dr. Jain: After adjustment for the

injuries was some of the stuff we reported. We didn't do multivariate controlled analysis for a lot of the outcomes that you saw. So those could have become less in line as well.

Dr. Newschaffer: Well, this is Craig again, just real quick, as we were entering into this conversation, the thought occurred to me that we did not pick conditions.

And perhaps we should have picked some conditions, where we would expect to see no differences, which would have been an interesting sort of sensitivity analysis to undertake.

But Anjali, my recollection is that we didn't, because of the scope of the project and the number of things we were doing, we didn't incorporate any of those checks. But that could be an interesting follow-up piece of work to do on this issue.

Dr. Jain: Yes, we sort of used injuries a little bit to get at some of those risk factors that were preventable, thinking that those would be the lead to potential interventions.

Dr. Kimbark: So I just had a question about some of your future research that you're looking at, especially considering infertility treatment.

One of the things I'd like to know is: are you considering teasing out the data for prenatal environmental factors, for instance.

A lot of people have been doing studies, in vitro studies, to see if in vitro fertilization increases risk for ASD.

But the question really is, that I'm looking at, is are you going to be able to tease out maybe possibly looking at the donor egg sub-set, where you have a donor egg genetic mother and then the surrogate, who eventually becomes the biological mother.

Are you going to look at those types of things in order to tease out the prenatal environmental factors that could cause some issues?

Dr. Jain: Well, for the last task, we did try to get a sense of both sample size, as well as to compare the prevalence of some of these treatments and things to the literature.

And so infertility treatments was one of the ones that seemed comparable in the comparison group to what's been reported in the literature.

So there is, I think, a potential opportunity to take those codes apart a little bit and to look at potential different types of infertility treatment, as long as they meant different coding.

And so I think it sounds like some of what you're saying might be possible, but perhaps not all. I don't know, Craig. Do you have something to add to that?

Dr. Newschaffer: Yes, it is of interest. I think that, as Anjali said, it was encouraging news that I think we saw, also I’m looking here at the detailed tables.

And we had about 9 percent of the moms where we had full coverage around pregnancy, suggested that there was some type of infertility treatment, which was within the literature ranges.

The trick is whether or not there's the richness of coding detail to tease those different types of exposures apart. I have a doctoral student working with a different private insurance claims database, who is focusing on this very question.

And we're a little bit uncertain as to how deep we can go. It has to do with the coverages that are offered and the way some of these procedures are coded.

So I do agree that it's an area that's worthy of further exploration. Whether or not claims databases will be robust enough to sort of get at that level of detailed exposure I think is still to be determined.

Dr. Insel: We'll work our way around the table, so just be patient. Cindy?

Dr. Lawler: Hi. Just quick, I'd like to hear your thoughts about the value or the feasibility of using a database such as this to look at specificity questions, sort of a comparison group of families with children affected by perhaps a developmental disorder, but not autism.

Did you think about doing that? Could you do that? How could that sort of help you look at some specificity issues around the outcomes and whether there's unique groupings in families with a child with autism?

Dr. Jain: Well, the study I would love to do, which I keep saying, is to try to use sort of the patterning of diagnosis codes to try to get at whether or not there might be meaningful sub-groups that would then need to be validated, of course, with some sort of clinical data set.

In terms of just looking at children with other developmental disabilities, we did include what we called an enriched control group for the chart study, to try to get at – be able to make more use of the smaller number of charts, in terms of understanding the kids that were perhaps not being picked up.

And it wasn't very fruitful in the sense of identifying children that did not have an autism claim, but had autism in their charts. We didn't find any of those kids.

But we did find kids that had other developmental disabilities in that enriched control group, and had selected them that way. And they just turned out to be a very different group of kids, in general.

And so I think that there's probably even, it's hard to believe, but there might even be greater heterogeneity among that group that has some of the contributing developmental diagnoses. That is really such an open question at this point.

Dr. Insel: Scott?

Mr. Robertson: So I think it's an interesting study, and some really interesting results. But I just have concern that maybe to regard some of the prevalence of conditions, for instance some of that data, with maybe some caution, given the fact that it's linked through the payment – that in having seen kind of first hand some of the things that go on in the insurance system and to get payment for treatment services supports for medical conditions on medical depression, mental health, et cetera – sometimes using a code of depression when the person maybe has other things but the provider wants to make sure that they get reimbursed for that, there's a whole system that almost, I hate to say the word game, but almost a game –

Dr. Jain: No, there is.

Mr. Robertson: – that's kind of played in these things. So I do worry sometimes that when seeing those numbers that people would say this represents an exact linkage to these conditions. Because sometimes it's harder through other means to find out rates for co-occurring conditions, et cetera.

So I would be a little skeptical to say based on singularly that data, that infectious diseases, all those other things, are higher.

The other thing that seems to me that could be a confound on this, unless I'm interpreting this wrongly, is that there may not necessarily, unless one has a comparison to non-autistic population, it could be that for some of these conditions, maybe families of autistic people, autistic people themselves, may be more likely sometimes to seek services, health kind of treatments.

So that might actually look different for the population of autistic people, family and supporters, than for the non-autistic population, until one does the study.

And more broadly, we don't even know if that might be one of the confounds. Or maybe more likely to seek reimbursement, maybe there's some economic kind of factors that are going on there.

So that's one of the things that one should look at with a little bit of a critical eye when looking at it, I think, sometimes these insurance data, is it doesn't necessarily represent a direct linkage to what's really happening on there.

Now, I don't know if you have plans on that, to do follow-ups with some other additional methodology, maybe some interviews, surveys, and more.

So explore some of these things so try to tease out some of these issues and see if maybe some of these things are going behind the scenes, that you don't see in that data but maybe could be found through other future methodology, that can find out if some of these things that maybe could be a factor, some confounds in there, could be at play.

Dr. Jain: Right. You're absolutely correct. And the data has all kinds of limitations. And luckily our colleagues at OptumInsight, they're really used to working with claims data for research purposes.

And this is a research claimed data set. And all the claims have been adjudicated, et cetera.

But just to give you an example, for depression for instance, or for seizure disorder, we allowed either two diagnoses on different days, different times, separated by a period of at least a month, I believe, or one diagnosis with a prescription for an antidepressant or an anticonvulsant.

So we had some of that thinking in mind, and knowing a little bit more about what's likely to get diagnosed and what's not likely to get diagnosed, and what's going to be in the chart.

And if you look overall at the data set, our prevalence of autism, just in the data itself, was about half of what has been reported in the general population. So we know –

Mr. Robertson: Oh, that there are already some concerns there at play –

Dr. Jain: Oh, yes, we know that we're missing a lot of kids. But the kids we are getting, I think the chart review study showed us that it's a pretty good chance they have autism.

Mr. Robertson: So maybe also in the

future if you have something that more represents the full population of autistic people, maybe you'd see also differences in what the data shows too.

Dr. Jain: Right.

Dr. Insel: Lyn, and then we'll come around.

Ms. Redwood: I had four really quick questions, I hope.

Dr. Jain: Okay.

Ms. Redwood: One is, are you planning more papers than just the two you've outlined? Because I think the findings, in terms of the gastrointestinal disorders, are really important.

Number two, I'm hoping that this will continue, we'll continue to have access to this database. I understand it's not perfect. But it's insightful.

The third thing I was wondering about, the early immunizations that you have listed as something you'll look at. Is that including the mother and the child?

And fourth, the fourth question, could you also look at immune globulin administration during pregnancy? Because that's something that's relatively new, that started in 1991 by the American College of Obstetricians and Gynecologists.

It affects about 12 percent of pregnant women, where they're recommended to receive Rho (D) immune globulins during pregnancy.

And I worry, with this concern with inflammation during pregnancy and oftentimes these are administered multiple times during the pregnancy, if there's any invasive procedures, or episodes of bleeding.

So I think that's another medication that needs to be looked at closely. There's been two studies already that have linked maternal Rho (D) status to autism risk.

Dr. Jain: Okay, I'll try to remember all your questions. But remind me if I don't. So we are planning more papers. But as for these findings, they will be disseminated in the reports. And we'd like to do more papers with funding and resources.

And we are hoping to continue this work, both for autism, as well as potentially for other conditions. We're exploring looking at some of the under-immunization and seeing if that has differences in outcomes as well.

In terms of immune globulin, I believe we can include that. However, I know that a lot of medication administration in an inpatient setting does not get coded as such. It kind of gets lumped in.

Now, IgG is very expensive, and so it might get coded separately. It would sort of depend on that. But usually I know for inpatient medications, our data is not so good.

Ms. Redwood: These would be outpatient from the OB/GYN records.

Dr. Jain: Oh, they're from clinical records?

Ms. Redwood: Yes.

Dr. Jain: Yes, then we should have it.

Ms. Redwood: Okay, great. Thank you.

Dr. Insel: Jan?

Ms. Crandy: My question is on the injuries. Did you guys tease out sports injury, because I know more typical kids would be involved in sports. And our kids might not be.

Dr. Jain: Well, we tried to look at some major sub-types of injury. And what we ended up finding is the overwhelming majority of injuries were coded as various types of trauma.

And so we were not able to do the initial analysis to understand the upstream mechanism for that downstream broken leg, or whatever.

We did do a separate analysis after, just recently actually, to make sure that we were mostly talking about unintentional injuries.

In fact, there's a very small percentage that are in our results that are actually intentional injuries.

But certainly we could do additional

analysis to get at the sort of drivers of injury and how that varies by various co-occurring conditions and age groups, et cetera. So that's certainly possible.

Dr. Insel: John?

Mr. O’Brien: So I think it'd be helpful, and you've probably already done this, is to look at what are the interventions that people are getting for these various conditions.

So for instance, I go right to mental health and the extent to which folks are typically getting inpatient services versus outpatient services, because you see a high propensity of inpatient services.

You maybe have a lot of questions about what do we really need to do for this particular population. The same is true in terms of looking at the extent to which somebody got medication for mental health reasons, but didn't get a correlating mental health service.

Not that one should always do that, but

we often that there's lots of meds being prescribed, but little services being received. So again, some thought about what those service –

Dr. Jain: We have some of that analysis done already, in terms of the different categories, inpatient, outpatient, behavioral health, et cetera.

Mr. O’Brien: That would be great to see. And then –

Dr. Insel: Before you go on though, can you just clarify in terms of John's question, can you actually tease that apart, to look at behavioral health interventions beyond medication?

Dr. Jain: Yes, we have visits, therapy, et cetera, yes.

Dr. Insel: As long as it's within the insurance?

Dr. Jain: Right. Just having in the data set the use of things like speech, and PT, and OT is quite low. And that's almost largely definitely due to coverage issues, or it being taken care of in schools that are –

Mr. O’Brien: This is commercial data?

Dr. Jain: This is private, commercial, yes.

Mr. O’Brien: And then the other thought that I had, it's along the lines of what John suggests, which is if we had the opportunity to look at older adults, are there certain conditions that we're seeing more prevalence on, both from the perspective of, gosh, do we have some issues relative to maybe life expectancy and what not.

But what does that also say about possible coordinated care models between primary care and those other conditions that, frankly, we want to start paying attention to. We know what some of those are for the general Medicaid population. But I think for the commercial population, and for this group in particular, we don't have lots of information. So I would think –

Dr. Jain: Right. Especially, I think, this data set is very useful for the pre-

Medicare, younger than 65. Because after 65 it really does almost vanish.

So that's one thing to think about in terms of once they get into Medicare the private insurance is not so good.

Dr. Newschaffer: This is Craig, can I just interject something? We’re just using these private insurance databases for studying older populations.

While I mentioned that I have much enthusiasm for studying health issues in older populations and individuals with autism, there will be challenges in using this kind of database.

Because of the fact that as individuals age, and we saw this even over the relatively narrow age ranges of from birth through 21, the frequency of ASD, claims with ASD codes really goes down.

So in order to identify older populations with ASD in the claims database, there's going to have to be a population that has a very long, continuous and relevant history. You've got to have confidence that you're really identifying a group of older folks that have ASD.

So while I think this data source should be considered for that type of work, I just wanted to emphasize that there will be challenges in identifying older groups in private insurance claims, who actually have ASD that will have to be confronted.

Dr. Insel: Geri?

Dr. Dawson: Yes. So I think the related issue is that you are interested in risk factors, right. And if you noticed, the last part of her talk was on risk factors.

And one of the limitations of this data set is that it doesn't have much longitudinally. If you notice, she said that the average span was 4 years.

And so as we think about using this information – and this afternoon, the Strategic Plan, and the need to understand risk factors for best outcomes as adults, and how to maybe even implement prevention efforts that could have healthier outcomes – we're going to need different kinds of data.

And one of the things to be thinking about is, do those data sets exist? Or is it necessary for someone to be collecting some longitudinal data, so that we can have some answers to these questions, maybe the CDC or others that are involved in surveillance.

It just seems really important. And these data sets are not going to answer those questions.

Dr. Insel: And the next thing on the agenda was the National Children's Study. But we may not get there. Let’s see, Idil?

Ms. Abdull: Hi, thank you so much for presenting this. This is even a good idea for states, when they are thinking what to pay, and for how much, and what have you, to read. I just have a comment about the in vitro, people doing in vitro. And it's interesting you said that, because in Somalia, people, when we lived back home, even in Africa people had children, like Catholics, every year.

But then you come to America and it's for some reason very difficult. And I don't want to start a whole new thing now, but I don't know if that's even a contributing factor of what's going on. And so that was interesting to hear.

My question is about the gastrointestinal or nutritional. Was it because, what kind of data did you collect? Did they have food issues, or nutrition?

Dr. Jain: We took a very broad view of that. So we included things like food allergies, insensitivities, as well as things like inflammatory bowel disease, that are more chronic conditions, diarrhea, constipation, encoprecis, all of those things were included.

Ms. Abdull: Which a lot of these kids have, okay.

Dr. Jain: Right. Because I think a lot of the symptoms themselves don't seem that severe, but sort of living with them can be devastating.

Ms. Abdull: Right, thank you.

Dr. Insel: Last comment, David?

Dr. Mandell: So I love your phrase, intoxicating strength. It may be my take home phrase from the meeting.

I have two related questions, picking up on something that Noah and Scott said about this idea of surveillance, or hospital or Berkson's bias, right.

That is the potential that if you have two conditions your probability of coming in contact with the health system is greater than if you have only one.

And once you come in contact with the health system, the idea that a second one could be picked up is much higher than it is in the general –

Dr. Jain: Absolutely.

Dr. Mandell: – population. And it seems like, so that could affect a lot of your observed differences between groups. And I'm not sure that injury is the best control for that. But I think it's a good start.

Dr. Jain: Right.

Dr. Mandell: But one of the intoxicating strengths of this study is the chart review. And a more in depth chart review, and perhaps linking those charts to people, this is more than just a sample of convenience.

In some ways this is really sort of the start of a population-based sample that you have the potential to get much more granular data on.

And I wonder. I know there are huge HIPAA issues, and that it's very challenging to get to those charts, and potentially even link them to other data. But certainly we do it with MEPS, right, with the Medical Expenditures Panel Survey.

And there may be other ways to leverage this extraordinary resource that you've developed, that's generated so much excitement, to have more careful data on a sample that could be followed for an extensive period of time, regardless of where their insurance moves.

Dr. Jain: Well, also as we move towards electronic health records, I think it really has the potential to provide that sort of long term longitudinal in depth clinical information.

So the injuries, I didn't mean to say that that was a control group. But we were picking a condition that we didn't think would necessarily be increased in kids – that were preventable and not necessarily related to autism itself. Although I know that there's lots of views about that.

We did look at, our sort of small attempt to measure surveillance bias is we controlled for preventive health care visits in the children.

And adjusting for that did not make a difference in the findings. But again, that's a highly imperfect measure of surveillance bias.

Dr. Insel: Well, Anjali, this is really a great review. Thanks to you and Craig for putting this together for the IACC.

I think, as you could tell from the questions, there's a lot of interest in what you've done, and a lot of enthusiasm for seeing much more of it as you go forward.

And it sounds like, while some of the data are already ready to go out there, there's still some pieces of this that you want to continue to explore.

And the good news is if it goes into NDAR it becomes possible for lots of people to begin to explore this. So that's great to have. Let me just stop by saying thank you. I think you deserve a round of applause.

(Applause)

Dr. Insel: We really appreciate both of you taking us through this. So we have more than used up the time for our break, and for Dr. Guttmacher's presentation, which actually in some ways was thematically right on the mark for talking about longitudinal studies, since that's what he was going to talk about.

I'm going to suggest that we take a

break now. I'll confer with Alan to see whether it's worth actually taking a shortened overview of the National Children's Study, or whether we want to put that off until our next meeting.

I do think it's really important for us to have a discussion about what the IACC's going to do, and how we're going to do it, going up.

So I want to reserve at least an hour for us to have that conversation. Let's do it right after our break. If we break now, I have 3:10. Let's plan to be back in 10 minutes max, so 3:20 we'll start.

(Whereupon, the Committee members took a brief break starting at 3:10 p.m. and reconvening at 3:21 p.m.)

Dr. Insel: Okay, we've got to get back to work. It's 3:20. We've got a lot on the agenda. Alan Guttmacher is going to say a bit – a very abbreviated version of the National Children's Study.

But we're going to do this. I prefer, if we can, to hold questions unless they're just clarifying questions. It's really important for us to have a conversation, which needs to be lengthy; about what you all want for the IACC.

We haven't done that yet. And we need to do it today. So, Alan, if we can go through this really quickly, that would be best.

Dr. Guttmacher: This is not everything you always wanted to know about the National Children's Study. It's everything we can fit in, in less than 10 minutes.

So, what is the National Children's Study. Well, overall this is what it attempts to do.

It's really to have a longitudinal study of 100,000 kids who we'll follow, many of them from before birth, but all of them at least from birth through until age 21, to try to understand the interactions of environmental influences using that term quite broadly, as I'll show you in a moment, and biological factors in growth, health, and development to really understand much better than we do, basically, the etiology of childhood.

So this makes it the largest and most ambitious U.S. long-term study of child health and development ever. And among its important characteristics are that it's longitudinal.

We just had the discussion before about the advantages of that, and that it really does broadly define environment. It's not just toxic smoke stacks and those kinds of things.

While it includes that kind of physical environmental influence, it also includes these other kinds of things, when we talk about environmental influences. So it's quite broad in its scope.

It's really in some ways a misnomer to call it a study, to think of it as that. Because usually if we say study we think it's designed to give us information on a specific hypothesis.

This is kind of hypothesis-informed, or exemplar hypotheses, but it's not designed to answer a specific hypothesis. The exemplar hypotheses are the kind of things to think about – “gee, if you wouldn't give us helpful information about this, why bother doing the study.”

What it really is, is a lot of data – data about kids’ growth, development, health, as well as biological samples taken at various points in utero and in childhood, and also environmental samples.

For instance, the household dust from the home, in which the kid grows up, it turns out dust is an incredible rich source to be able to figure out lots of things about environmental exposures, and other kinds of environmental samples as well.

And all of those things obviously link to each other, which will be available. The data that this gives will be available to any researcher.

They don't have to be somebody that's funded directly by the Children's Study or anything else. There will be also a way to apply for use of the specimens.

Obviously the data is not limited. It's electronic data. It can be used an infinite number of times. The specimens are limited, so there will be a process by which people can apply for use of those specimens. But if they use those specimens, and really measure some kind of cadmium levels in the placenta or something, if that is done then all of that data becomes freely available to everyone.

These are examples. And I stress this example is about the kinds of physical, environmental, and other environmental exposures, and the kinds of health outcomes, developmental outcomes, growth outcomes, that the study is interested in looking at.

And again, this is not a complete set. It's the kinds of examples of the kinds of things it's interested in.

You'll notice here autism features as an example. I'll come back a little bit later for some specific information about autism.

There are three major components to this study, the vanguard or pilot study, which is between 4,000 and 5,000 children, which was started in 2009 at 40 geographically-diverse sites across the U.S., which is really designed to be a pilot study, to inform the main study as to scientific issues, logistic issues, cost issues, et cetera.

The main study, which will have about 100,000 children, is planned to start this year. But the first enrollment of children will really be next year. So children will be enrolled probably 2014 through 2016, is what we think at this point. And there are also formative research studies, shorter-term studies, which are really methodology studies and other kinds of things, which we can talk more about too sometime.

Now one way to think of this, one of these lines that are particularly pertinent here, of course, is that of the 100,000 children, assuming current incidence and prevalence rates, which may change for all of these, but assuming that, these are the kinds of numbers we would expect to have.

So again, if we underscore that these kids will be born more or less 2014 to 2016, if you tell me what the incidence of autism is in those years I can tell you how many of 100,000. Because these kids will be representative of the U.S. population in many ways.

So we would expect the rate of autism in this group to really be very close to the national rate of autism. It's not designed to figure out rates of diseases. That's not what it's designed to do.

It's designed to figure out the roll of various influences in kids' health. But we expect the numbers to be roughly equivalent to what we'd see if we did sample the entire U.S. population.

So depending upon what numbers one believes, especially projecting the future, one to several thousand kids who will fall someplace on the spectrum. Now the (unintelligible) national probability sample to be generally representative of the U.S. The recruitment will primarily be through healthcare providers, two kinds of strands of this recruitment: a birth cohort, which will be via selected hospitals and birthing centers across the country; and a prenatal cohort through prenatal providers and clinics that refer into those hospitals and birthing centers.

Again the total sample size will be 100,000. We expect that those 90,000 to come from this birth and/or prenatal cohort, probably something like equal numbers in those two cohorts. That's still being figured out.

And then another 10,000 that will be added, some of whom will be a preconception cohort. So we'll have data even before conception. But also we will be looking partly at the enrollment in the 90,000 if there are specific populations, particularly disadvantaged populations that we think are under-represented in that 90,000, we’re going to do targeted recruitment, to make sure those populations are adequately represented.

So a couple of specific questions you might ask. If kids have autism, when will this study discover when during their lives will they do it?

The current plan for the main study, we would guess it'd be someplace around 18 months of age. But, as I'll get to in a moment, there may be other ways to do it somewhat earlier.

There's also, with the access to medical records for kids who are diagnosed somehow outside of the sites of their usual care for instance, as having autism, we'll be able to pick that up through their medical records.

And this is a good point to mention that we have a policy in the National Children's Study that results for medically-actionable findings will be shared with parents and primary care providers, depending upon exactly what parents request before they enroll, of how they would like information shared.

So for instance, obviously the diagnosis of having a child with autism would fall in there as an actionable finding. It would be up to the parents to let us know ahead of time what they would like to find out and how.

So might we think about other instruments besides those in the first slide for testing kids who happen to have, for instance, elevated risk for autism, maybe because of family history? And the simple answer to that is yes. And that in fact already, as part of this form of research effort, there's an ongoing study now, a multicenters study representing a number of major academic centers with expertise in this, which is comparing a battery of three brief novel assessments of video-guided parent self-report, a parent interview and a direct observation, all of which could be used by National Children's Study field staff and to see how that compares to the "gold standard," case confirmation through the autism diagnostic observation schedule by research-reliable assessor and a *DSM*-based diagnostic assessment by a qualified clinician.

We expect the results of that study to be available later this year. And of course as with the many formative research studies, it will be helpful in planning the Children's Study itself, but also helpful for lots of other research.

So in summary, it's a large longitudinal data collection of 100,000 kids with linked biological and environmental exposures. And we really do think it's an unparalleled resource to understand childhood health, growth, and development.

So speaking quickly, how might else it be used to look at autism? Let's say that 7 years from now someone has an observation that suggests maybe cadmium levels in utero are a risk factor, high cadmium levels are a risk factor for autism. And I have no reason to believe that's the case, okay. But let's say somebody says that.

Well, how would we look at that? Well, we can actually use the Children's Study to go back where we will have 1,000 to a couple of thousand samples taken in utero of maternal blood levels.

We would have placentas we could look at and measure cadmium levels in those 1,000 or couple of thousand kids diagnosed as having autism, compared to lots of very well matched controls, and see, do the cadmium levels really vary or not.

So there are certain kinds of things that would be extremely useful for. There's other kinds of knowledge it'll be of no use whatsoever in trying to figure out.

So I think it'll be a very useful new tool for us, not just in understanding autism, but lots of things about child growth, development, et cetera. And again, that's a very quick overview of it.

Dr. Insel: Thanks, Alan. Given the time frame, unless there are any really burning questions, I want to move us along. But I did think it was important for people to hear about this.

And it actually is relevant to the previous presentation, where we heard the need for longitudinal assessments, but longitudinal going into adulthood as well. So whether there'll be a national adult study at some point –

Dr. Guttmacher: Some people suspect that at the age of 21 these kids may still be, although they'll be adults then, they might still be worth following. But we're not funded to do that.

Dr. Insel: Okay. Let's move into this other discussion then, thanks very much, which has to do with the role of the IACC in how we meet our charge. Susan, can you take us through?

Dr. Daniels: Sure, I was waiting for the clicker.

Dr. Insel: Okay.

Dr. Daniels: So in this presentation I just want to go through quickly our charge once again, before we start talking about what we're going to do, as well as some of the things that are already underway.

But before I do that, I just wanted to quickly introduce the newest member of the OARC staff, Hope Sipocz, who's sitting at the desk over there. She's waving. She's our new science writer, coming to us from the U.S. Department of Agriculture. So welcome, Hope. And I guess this has been an interesting meeting for her to get used to what kind of work we do here at the IACC.

To get started on the IACC business our responsibilities under the Combating Autism Act and CARA are to coordinate HHS activities; provide advice to the Secretary of Health and Human Services; to establish autism priorities, and this is done through the *IACC Strategic Plan for ASD Research*; to communicate advances in the field, which we do through the IACC annual Summary of Advances in ASD Research; to monitor Federal activities and research trends, which, in part, we do through the IACC ASD research Portfolio Analysis report; and to serve as a forum for public discussion.

So just as a reminder, we have a current standing IACC Strategic Plan for Research, a full plan that has areas of what do we know, what do we need, and research objectives. That was completed in 2011.

And we have a brand new IACC Strategic Plan 2012 Update that is available on our Web site under the materials for this meeting.

It will be publicly released this week, officially on our Home page, but that hasn't happened quite yet. There were some copies outside on the table. I heard that they're gone.

They were the pre-publication drafts. And we're going to be doing the full run of printing in the coming couple of weeks. But this document that you've been working on for the past several months, and put a lot of effort into, is now available on our Web site. And it answers the questions what do we know and what do we need for the seven question areas of the Strategic Plan.

So, we have to talk about the 2013 Strategic Plan update that we're required to do under the Combating Autism Act, and the Combating Autism Reauthorization Act.

So what kind of a product do you want for the 2013 Strategic Plan Update? And then we can talk about what kind of process to use and the time line for that. And we are delimited by the end of the year. We do need to complete an update by the end of 2013. So that's open for discussion.

Dr. Insel: So before we get into the discussion, let me frame what I think is a maybe a little more complicated issue. The Strategic Plan is largely about science. It's what research needs to be done to answer the main questions.

As we got into the update, it became very clear very quickly that the most energy was around questions five and six, five having to do with services and six having to do with adults.

And a real intense discussion that began right away about all of the things that needed to be done in that arena that were not being addressed, and thanks to, I think it was David and Donna who, is that right?

Dr. Daniels: Denise.

Dr. Insel: David and Denise, sorry, who fielded those discussions, and to their credit were able to get people back onto the question of, well, all these things are important, but what really needs to be done in terms of the research. And what is the narrow focus of that.

But I think what was perhaps more important for us to hear as a Committee was the needs that so many people feel that are urgent, and have not been addressed around services, something that is in our charge in the statute. It talks about the IACC's responsibility for educating the Secretary about issues as they emerge that are relevant to the public health for people with autism.

I bring this up because I've been thinking a lot about it. And I, just this morning at something like 6 a.m., received an interesting email from a parent and advocate who said that, who was also quite frustrated with the IACC, said that the things that we haven't addressed are that autism remains a have and have-not disorder.

If a child with autism comes from a family with wealth, insurance, and access to leaders, that child tends to do so much better than a child, whose parents struggle each day financially and lack the ability to have access to leaders.

Point 2, the autism community is one of wonderful people, but more approaches to cause treatment and services than any I've ever seen among any group of people. And far too much of what occurs lacks outcome-based analysis.

Point 3, there's a significant lack of services for adults, if any. And transition among life stages far too often just doesn't occur.

Four, every parent including my wife and I worry about, who will be there to help our son when we can't help him any longer or when we've died.

Autism is much more than a condition of the human body. It's discrimination, denial of rights, lack of opportunity. And our society continues to not provide for the inclusion and integration into society of people living with autism and a diagnosis of autism.

Like almost any other developmental disability, oftentimes one's life sentence to being discriminated against, denied educational opportunities and employment, among many other denials of life's pursuits.

I've heard that in one form or another in many, many venues. And I just thought, partly because it came just as I was about to leave for this meeting, but also because it does seem to me that those are many of the issues that people are facing that they feel IACC hasn't been helping with.

And so the question that I want to also help you think about is, is there a role here. Is there something we can do in the realm of, whatever you want to call this, provision of services, or just reducing disparities, or even social justice, where is the mandate for this Committee?

And do we want to go that direction or not? We can do, really, as a Committee at this point, we can do anything. But we can't do everything.

And we have to think about where in – what do we have, 18 months, 20 months left – in our charge, what we want to do in terms of our directions during that time. Scott?

Mr. Robertson: So one comment to make on that is I wondered are we limited to the format that we've had in previous Strategic

Plans where it is segmented, say autistic adults into a section service, into a section center, because a lot of these things tie together. It can't be easily so separated.

And I think particularly for autistic adults, to me it would be nice to see a recommendation put out there on the floor to see life span issues across the plan as a prioritization.

Not saying, well, we've got adults here, and then we've got children here, and the rest of the other four of five sections to think about autism more from a life span perspective. And then to be thinking about maybe have a prioritization on all these kind of unmet needs, and what are we doing about that across the life span.

And then how do we have any creative solutions in the research arena and outside the research arena that could be addressing it?

I know it's particularly because of my background, but I'm going to mention it, is like the technology arena. It's been a concern of mine that I feel like it's just assistive technology hasn't been emphasized as much as it could be in previous plans.

And that's, for instance, one element across the plan that could be part of novel ways of approaching some of these disparities, some of the things that are going to be happening in the disability community more broadly as we think about the fact that maybe services themselves, people, can't necessarily address needs, can't necessarily be there to prompt and support individuals.

But sometimes technology, great sensors, and smart homes, things like that, are going to be evolving in the next few years. And how can we fit that into when we're thinking of addressing some of these gaps in service and support systems for autistic people as they age through childhood, adolescence, adult life, and senior citizen life.

Gee, that's another kind of area in

terms of later life that folks in Pennsylvania, some of our folks at the state government level have actually visited residences of senior citizens, senior citizen homes of autistic adults is who never received the appropriate service and support systems years ago.

And you can see the gaps there in terms of what it's meant for a negative impact on their quality of life. So even thinking about that too.

And this is what I mean on the life span issue, is that you have to be thinking across, I guess we're so trained to segment these things, that it's a harder thing to be thinking about we can have this glued around the plan of across the life span, and thinking with an eye toward health disparity gaps for autistic people across the life span, and how we're going to meet that through research and things outside research.

Dr. Insel: And it would be interesting to see how your colleagues look at this. I guess what I wanted to suggest is I don't think we need to feel ourselves entirely limited by what the research Strategic Plan is about. There are other venues here. Alison?

Ms. Singer: I think we need to look at the CAA and the CARA legislation as a floor, not as a ceiling, so that it outlines the minimum that we need to deliver, but it's not exhaustive.

And I think one thing that emerged during this iteration of reviewing the Strategic Plan was a real need and desire to focus on not just services research, but on services delivery, and services implementation. And I served on Chapters 2, 6, and 7. And issues of services delivery and implementation came up constantly. And we were forced, many times, to say, well, that's really not research. So it doesn't fit here.

So my suggestion is that we need to create a mechanism whereby services delivery and implementation is equal in stature, and is represented as being as important as the research.

So my suggestion is that we think about creating a parallel document that would focus on a Strategic Plan, or a roadmap, for services implementation and delivery. So services research would remain in the research plan, but delivery and implementation would be in its own plan.

Dr. Insel: Yes, so this is I think something we really want to think about as a group. And whether to call it a Strategic Plan, or an action item, or an action agenda, lots of ways to think about this.

One point I would add to your comment, Alison, is that we're at a very critical point in time with parity becoming implemented over the next several months with the Affordable Care Act being implemented. There's a lot of urgency here if we're going to do something to make sure that we are able to both collect the information as it can be understood, but also to make recommendations or to let the Secretary know where the concerns are.

We may even be too late already. But I think if we're going to do this, there's definitely going to be a push to get it done quickly. John?

Dr. Ball: Alison, I'm sorry, just as a point of clarification, how would that be different from the roadmap that was already designed? Because that would be my concern?

Dr. Insel: You mean the roadmap from the last –

Dr. Ball: Yes, from the services.

Ms. Singer: You mean the roadmap that we did two IACCs ago, the services delivery roadmap?

Dr. Ball: Yes.

Ms. Singer: I think there's a lot of room for improvement over that existing roadmap. I think the General Accounting Office of the Federal Government, when it reviewed that roadmap, found it to be one of the worst documents produced. I think it was sorely lacking. And I think it can certainly be improved upon.

Dr. Ball: Well, that's what I wanted to hear –

Ms. Singer: Okay.

Dr. Wexler: Tom?

Dr. Insel: Yes, speak.

Dr. Wexler: Tom, this is Larry Wexler. I don't know if you can hear me.

Dr. Insel: We can hear you.

Dr. Wexler: Oh, great. Well, I would support the idea of actually making an effort, whether it's through a document or whatever other means, to actually coordinate – which is what the IACC is supposed to be doing – service provision, service research. I mean we have multiple offices within the Department of Education that are involved with autism, certainly our Institute of Educational Sciences, as well as the Office of Special Education Programs.

But we would be most interested in having the opportunity to actually sit down and talk through who is going to invest in what. And more importantly, how can our investments – given the limited dollars – how can our investments complement each other. So we would support some additional work on services. Thank you.

Dr. Insel: Geri?

Dr. Dawson: First with respect to, I think, the point that you're trying to make, which is that we need to act now around several urgent more policy-oriented issues.

And even today as we spoke, many issues came up. I brought up right away the healthcare exchanges and the fact that autism is not being included in that.

John talked about how is social communication disorder going to be handled, when we think about it from the point of view of defining it for insurance companies and others that are going to be making decisions around care.

We talked about prevention, and the utilization of the National Children's Study.

And we talked about ethnic disparities. All of those have, I think, two components.

One is a set of immediate recommendations that we could make as a Group to the Secretary of Health, and to Congress, because there is a Report to Congress as well, around things that we feel urgently need to be done now, that we don't need to do the research for.

And then I think the second set are some targeted questions that are research questions that need to be addressed.

And I would say that although we've done this wonderful landscape of objectives, this time around it would be nice to define at least a handful of important studies that we would recommend be implemented, right.

So I know we can't do that, we cannot dictate to NIH what they fund, or the Department of Health. But there could be a set of very targeted projects that we would say, you know, these really need to be done.

We've done that on a small scale with

wandering and other things. But maybe the time now is to get a little bit more action in our recommendations, and not just this passive document that I think has had some influence, but not the kind of influence that we need, or the urgency.

Dr. Insel: John?

Mr. Robison: To the end that we want action, one of my greatest concerns that, really, as I've seen in my time serving on these Federal committees, I see that the public's frustration is growing, not diminishing.

And I feel like we are not serving our constituency. We are not, with all the millions we've spent, making the lives of autistic people better.

We have identified many, many things that will make our lives better. We've identified various therapies, services, and treatments that are effective for different people at different points on the spectrum. And yet, those people can't get those services and treatments because they aren't covered by insurance, they aren't covered by Medicare, there are no people trained to deliver them.

There are a variety of reasons, but what it comes down to is the stuff that we are spending our hundreds of millions to develop doesn't matter to the public.

And what we need to do, and I feel this very strongly, we need to deliver value with what we have already paid to investigate. And I think that we have some specific things that we have hit upon here.

First, I think that we are at a critical time juncture, where we should form some Subcommittees right here and now. And we should formulate some letters for the Secretary and Congress about what we need to be doing. And I volunteer to be a writer and work on that, like the Sandy Hook thing. I think that we need to ask NIH and CDC to spend more of their research efforts to validate and do back-up studies to determine which of the therapies we have already developed, and had positive reports on, which of those are the best.

I hear time and again from our lobbyists at Autism Speaks, for example, that insurance won't pay for something because there's no base of evidence that it works. And yet I hear at IACC that, oh, we did this study at UCLA and 30 kids had a great positive outcome from it.

Well, 30 kids isn't enough to make insurers buy it all over the United States. And I think that's our job, to tell CDC and NIH that we need you to take that study, run with it, go study it in 10 more places around the United States, and bring us something that we can get covered by insurance.

And at the same time, bring it to Medicare, bring it to the Department of Education. We need to take what we've developed and turn it into delivered value for our community. And we've got to start writing that now. And it's not a report. It's in letters.

Dr. Insel: Matt.

Dr. Carey: I think what Alison said is actually very well taken. I think if you look at the laws, it's an extremely broad mandate to advise.

There's not a real limitation to what we can do in that respect, in terms of giving advice. Now whether people accept our advice is another matter.

But I would say to look back on something that was very successful, if you look back on fighting for, say, ABA therapy by insurance was never an easy battle.

But it was a lot easier for people who use – but you made a very strong statement at one point. There was a statement by the AAP, and there's a statement by the Surgeon General, I think. And people, who incorporated those into arguments with their insurance companies, were able to win a lot more than, I think, the people who didn't.

So I don't know if we are starting to

move towards an idea of best practices or something with this discussion. But giving that kind of advice, f something that people can cite back and say, look, here's what somebody says.

I think the Strategic Plan works very well for what it is. But it works like a scientific paper, right. We've got a lot of data from a lot of different sources. And we come to some conclusions of where to go from there.

But it's not as much advice. It's advice of where to go, but not advice of really digesting the information for people.

And I do think that, like I said, those examples I gave. I think they didn't knock down the doors, but they were a key to help people open those doors. Not everybody, but –

Dr. Insel: So we're going to just go around the table again. Because I think this is a discussion we need to have. And I really value everybody's best thoughts about this. Donna, are you next, yes.

Dr. Kimbark: I just had a couple of things to say. At the DoD, at the Congressionally Directed Medical Research Programs, what we were tasked continually from Congress about is applied, applied, applied, translational research, translational research.

And I think Alison has a really good idea about a roadmap about services, and that research that we actually are supporting, or are suggestive of, should really take that into account, that it should slide right into a roadmap for services.

Because really a lot about, in an economic crisis that we're in today, we really should be answering the question of how we can improve the lives of individuals who are living with autism now.

I've talked to many, many advocates. And what they've told me over and over again is that they sit in these scientific conferences and what they're seeing is, oh, this is the data that we had, and we'll be able to help you in 30 years.

And they're dealing with it right now, today. Parents are dealing with this right now today, family members, caregivers are dealing with this right now today. And I think that the IACC should really be pushing for research into services and going forward in that way.

Dr. Insel: Cindy?

Dr. Lawler: I just have some related thoughts that I think many of us have feelings of dissatisfaction with the current way we update this Plan. And it really has to do with how we evaluate progress from last year.

And echoing some of the comments, the progress is always these high profile papers published. And that's so far disconnected from the ultimate impacts that we want to have.

I know in past iterations we had aspirational goals that would be more of the long term impact. I think we dropped that. So now we just have, we're publishing papers.

But there's no logic model framework, or some other framework to really understand how you get from those basic science findings, or hearing somebody that has data, to really having an impact on the lives of families with the disorder.

And, yes, it is going to take some time. But to not have this Committee really understand how you get there, or lay out some way, so that for the next year we can be looking at not just the papers.

But are they really on the path toward are there proxy measures, intermediate markers that we're getting towards those impacts that are somewhere between publishing a paper with 30 people and ultimately getting a better service delivery model.

Dr. Insel: So, Scott, I'm going to skip you because you already had a chance to talk. And there are lots of other hands up.

(inaudible comment.)

Dr. Insel: Okay, we'll get to go to the

FDA for this.

Dr. Farchione: Well, it's not really an FDA question. But I guess I have sort of a logistical question. So if we're talking about we have these ideas that we think these are gaps, and we need to address them and everything, and we have some ideas of the kinds of studies we'd want to see, what kind of product are we able to create that's going to have some impact on that.

And especially when we're talking about this urgency, it would suggest that including something in the next update of the Strategic Plan, it probably isn't fast enough, that we would need something sooner if we want to influence implementation of the ACA and the health exchanges and things like that.

So what can we do between now and like for instance maybe the next meeting? What are the kinds of options that we have available to us?

Dr. Daniels: I think it might make, this is Susan Daniels, it might make more sense for us to talk about what you want to accomplish. And then we can talk about what process would work best.

People have brought up a couple of ideas, for example writing letters to the Secretary, some sort of a roadmap document. But maybe if we first figure out what it is, what topics you want to focus on, and what kind of thing you want to do, it might lead toward what type of product you want to create.

Dr. Insel: Lyn?

Ms. Redwood: One of the things, actually two, real quick, one is it's very frustrating to be having this conversation at 4 o'clock in the afternoon.

Because to me this is the most important discussion that we're having in terms of how we're going to move forward as a Committee.

So one of the things I would want to propose is these updates are important. Is there any limitation to having these meetings last for 2 days?

You've already paid for the travel for us to be here. We need more face time as a Committee to be able to do this important work.

So either move these types of discussions further up in the day, because it's very frustrating when we get down to the real nuts and bolts of what we're going to do as a Committee that we're always time constrained by that. So that's Number 1.

Number 2 would be I really think that we shouldn't scrap this. And we've got what, four Strategic Plans now. It's time to assess what we've done the last 4 years. Because we can't move forward until we look at what we've accomplished and where those gap areas are. So I would recommend that we go back and look at this plan.

We wrote these objectives to be smart, where they were measurable, they were time bound, they had dollar resources allocated to them. Let's see what we've accomplished.

So I just really want to put forth not

to scrap this plan, because we've done that before with the first combating, what was it, the Children's Health Act, the first IACC that wasn't a FACA Committee had a Strategic Plan, worked very hard on it, had an update. And then that was sort of scrapped when the new CAA started.

So let's look at this too, to give us some idea of where we were, and what we've accomplished, and what we need to do differently.

And I agree that we do need to put out RFAs. We need to target the answers that we need now. And I understand the importance of services for individuals with autism. But I think it's equally important to try to stop this disability, and to focus on prevention as well.

Dr. Insel: Jan?

Ms. Crandy: The roadmap idea, I think it needs to be a Federal guidance document that comes down from the Secretary. There are so much disparities across states in what access is available, insurance, Medicaid.

I think that Medicaid needs to be a Federal mandate that addresses autism-specific treatment, supports, and services, and looking at the scope of what is that.

And we provide that guidance. And it comes from the Secretary of the State. And I think that the exchanges, we have to fix that insurance, even with those mandates. It is broken. And recommendations need to come from this Committee on how to fix that.

Dr. Insel: Understanding that all we can do is, we're advisory, so as others have said, we can send a letter, or we can put out a document. But there's a limit to that. Cathy?

Dr. Rice: So following up on what Lyn said, I felt like this morning is a very encouraging important discussion about the passion and focus on services. And I think this Committee has done a great job in terms of organizing and prioritizing research.

We don't have the ability to say exactly this must be funded and here's where the money's going to come from. But it really has brought a lot of coordination together.

So I certainly agree in not scrapping it, but thinking about how to move forward in a smart way and thinking about the translational aspects of it.

But I also heard from Alison that what we're also talking about, are we talking about a completely separate plan? Because even in this discussion, when we've been talking about services, we're still talking about services research.

And that's quite different from certainly whatever services are provided, hopefully should be informed by research. But the reality is we don't always have that. And the reality is how do we get meaningful supports, full access to all people that need them across the life span now.

And that's a very different conversation than we've been having here in the IACC. I think we have a great opportunity with the make-up of this IACC than we did in the past iterations. And that we have much more diversity of voices and experience.

But I think we have to decide. Do we want to give equal weight to a on the ground, how do we provide coordinated services and supports that are meaningful to those people that are the target of those supports, and are included in them across the life span. And it's a lot of work.

So if we say, yes – and I think one of the problems that we had in the last iteration of IACC with the various roadmaps, and we had lots of workshops, is that it was always the back-room sister, the one that at the end of the day we'd get the quick update from it.

And it wasn't the focus, it was not our priority. So if we're going to move forward with this, I strongly suggest that we make it as full of a priority as the research plan, and to put that into practice, how to actually improve the coordination, access to services, and what those recommendations may be.

Dr. Insel: John?

Mr. O’Brien: I can't speak on timing. I think timing's important, but I also know that timing can be the enemy and not the friend. And so I think part of what I said the last meeting is that whatever we do needs to be digestible to a number of audiences.

I can tell you that the Strategic Plan Update is good. And it's interesting. But I think for people that are making decisions about coverage, or trying to make good decisions about coverage, that plan isn't as helpful as something that would be able to say, gosh, here's some good outcomes that we need to be paying particular attention to for this population.

And it's not just a handful of outcomes. We know that there's probably several, or many, depending on different populations, disparities, ages, and what not. But also here are some interventions that you may want to be thinking about when you're developing your coverage.

Because I don't know if that exists out there for services for individuals with autism.

There's some really terrific work that David's done, and other folks have done. But again, trying to make it digestible for payers, I think could be really helpful, and would hope that we could do some of that this year.

Dr. Insel: And that would be a separate document from –

Mr. O’Brien: I care not about format.

Dr. Insel: You want the information. Idil?

Ms. Abdull: I agree with almost everyone here, or everyone, that's a first, right.

(laughter)

Ms. Abdull: And I think Lyn is right that we need to keep the Strategic Plan that we have now in terms of research. Because I'm always baffled by when people talk about autism, we are so against each other.

I don't know if you guys remember Michael Strautmanis when he said 2011, he said we fight so much that we scare researchers away, right.

And I'm the first fighter. I always like to pick a fight. But as I get older, and I listen to you, and I learn from you guys, I realize that in order for us to, we have to look at autism as, yes, we need research to find a cause, to find a cure, and to prevent it. This is not an easy disorder.

But also we need to support that people have it, that we need to figure out they're here. You can't go back yesterday. So we need to get what Alison was saying. We need service delivery.

In addition to this, we need to tell the states, because right now it's who's the biggest lobbyist, who's stronger money, those are the people that are getting their behavior therapies, or the developmental behavior is stuff that's being recommended.

It's who has the bigger buck.

And we need to do it in a way that Medicaid and also private insurance are working hand in hand. You guys need to marry each other.

Because when we talk about disparity, many poor people who are low income, are minorities, have Medicaid. So when we always say private insurance, they're exchanges.

The Affordable Healthcare, it doesn't cover Medicaid, right. So we have to make sure that the service delivery, and we have some sort of a document, and as John said, it doesn't matter what process we use.

But then we need to let states know this is what we came up with, this is what we recommended to the Secretary, and sort of use it as a resource guide, or a guideline.

And the last thing I would say is, which is already our charge, the coordination part, right, we're supposed to, Federal activities.

And I don't know how many people I've harassed here about saying what do you do?

Learn the science. From who? What if I don't have a computer? I don't have access to online. Learn the science so you can act early.

Okay, I got the science. How do I act early? Get the intervention. But they don't pay for it. Diversity, how do we make sure HRSA is funding, not 43 but, I don't know, 60 LENDs. How do we make sure that we're recruiting people of color?

So we need to have a coordination from all the Federal agencies, as well as the private agencies like the big ones, Autism Speaks, and yours, and what have you, so that when you are a parent, you have a roadmap of what to do and where to get it, and it makes sense, if that makes sense.

Dr. Insel: Great. Other comments, Anshu?

Dr. Batra: So I'm sitting here as a parent. And I'm one the haves. So I have fortunately the access to services, and some financial resources to provide services for my son. And he'll get it.

But in my practice I have way too many have-nots. And that's where I struggle. And I am frustrated with the disparity. And I struggle with how to help the majority of my practice.

And I go back to a very basic concept, at least in my mind, which is research drives services. And this is a phenomenal research document.

I think we all spent mega hours generating it, and vetted it. And I think it's a very good document to help us figure out what's up to date in research right now.

And I think we can't let this go. And we have to take it. I agree with Geri, and John, and everyone here at this table, that we can't let this go.

We have to take it, and make it even more succinct, to very, very few bullet points to say, all right, this is the research that's been promising in the last 18 months.

We have to take it and now see if it's even more promising. And if it is, great. If not, then we'll find something else. And then if it is promising then we provide a document, like Alison said, to then help the have-nots, provide a roadmap.

And again, I see it as a parent. That this, my eyes are already glazing over. And I'm a parent that knows a little bit. But most parents don't, and they don't even know where to start here. And a lot of the words are complicated, and they don't know how to read a scientific document.

We have to make it something easily accessible, a roadmap, simple, that my 12-year-old could read, that is validated, that if I'm going to pay my money, my hard-earned money, then I'm going to advocate it for my have-not patients.

And that's what we have to keep in mind here, is provide a document that is usable, that is validated, and that is going to be useful for the people that we made it for.

Dr. Insel: Yes, so I think you bring up an interesting point, which in some way synergizes with many other people around the table.

This document was written for the research community as a guide to tell people this is where we hope you will go and this is how we hope you will do it.

But I think what you're hearing from so many people is that's only one stakeholder in the world that we need to respond to. And the question has to be asked, how are we responding to the needs of families, of payers? As John says, how do we provide the information that payers are looking for. I get these calls all the time from insurance companies, saying I understand that ABA's pretty good, but what's the dose? How much should I pay for?

And they're always looking for the scientific backup. And we don't have any sort of document. The IACC has not gone into that space. But as far as I can tell, there's nothing to inhibit us.

As Alison says, what we have in the

statute is a floor, it's not a ceiling. And we can take this in that direction if the Committee wants to. It's really going to be up to you. Walter?

Dr. Koroshetz: So I just had a thought which may be inappropriate, but trying to marry the research side with the policy side. It seems to me the glaring piece that's missing is that we don't have a measurement tool that is sensitive enough to detect change over the spectrum.

And so I think it would be difficult to approach insurance companies with a study that used one scale that's only good for people within this age group, and say everybody should get this.

So that's an exaggeration, but I think that one thing this Group could do, if they wanted to, it would be very difficult, is because you represent the entire community of both the caregivers, the patients, and the researchers, is to try and come together and build a sensitive tool that could be used to measure severity that works all across the spectrum.

Now, we did this in TBI. We had an interagency group. And we ran into the same problem. We don't know how to measure outcome, we don't know how to stratify TBI. And we basically got everybody together and we locked them up until they came out with something.

(laughter)

Dr. Koroshetz: And it's not perfect, but it's something to start with. And I'm just taken by the fact that there are these tools, like the PROMISE tool, which was done not by biologists but by educators who are really good at asking questions and, depending on the answer, plotting where you stand on a spectrum. And it's statistically fantastic. You don't ask the same questions to everybody. Basically the questions you ask depend on where you start to look like you are in the spectrum. So if you're on one end, they detect that pretty quickly. And then your series of questions are very much dependent on where you on that end.

If you're on a much better end, similarly the questions that are used, or the tests that are used, are specific for somebody on that end.

But it's statistically a great tool. And it's something that, if it was useful, it could be used for research. But what you'd like to do is to have it in practice, a tool that could be used so that a parent knows where their kid is, and where he was last year compared to this year, and if he gets a therapy is there something you can detect.

Now it's a tough thing, but I think only a Group like this can do this. It takes a national to effort to bring everybody in to do it. But it's one thing that could potentially help, a concrete tool.

Dr. Insel: David?

Dr. Mandell: I'd like to come back to two things you talked about, impending policy changes and social justice.

So I like roadmaps for families. I don't like them for Federal agencies, or for funders. Because roadmaps for families are great. They help them navigate the current system.

Roadmaps for payers, for Federal agencies, either are paralyzing because they are idealized versions of what the service system should look like, that have no necessarily match, or relevance, to what the current system looks like. And 100 recommendations is often as good as none. Because you don't know where to start.

But we are in this very interesting position of having pending drastic policy changes in the U.S. that are going dramatically affect, or have the potential to dramatically affect, how people with autism get care.

And I think if we want to be helpful, and we want to be relevant, then we should be the body that is making very specific recommendations about how those policy changes get implemented.

And Geri spoke to this, and John spoke to this, and a number of other people have talked about it. But if we would like to, in fact, avoid the iceberg rather than rearrange the deck chairs, I think that is where we should be focused, on the Affordable Care Act, on what Medicaid expansion is going to look like, on what entitlements for adults with autism are going to look like, and to have very specific recommendations that fit in to the language and the current infrastructure of the organizations that pay, or will pay, for that care.

The second priority is, you may not applaud after the second one, is the social justice aspect. And we have danced around the issue of disparities a lot. And we have put it in our documents a lot. And we reiterate it a lot. And we probably don't need another study that shows there are disparities in care.

A lot of those disparities are probably

geographic, and a lot of those disparities are probably systemic, that is where most people, who are underserved minorities, get care is in the education system.

If you look at the ADDM data, or the CDC studies, and you look to see where people got diagnosed, people of color don't get diagnosed in the healthcare system. And they don't get care in the healthcare system. They get care in the education system.

And if we want to reduce disparities, one approach is the idea that a rising tide lifts all boats.

And when we're thinking about those Federal policies, and we're thinking about where we want to target our efforts, it's important to develop culturally-appropriate materials, it's appropriate to get to parents in communities that are traditionally underserved. But that puts the burden on the family.

And we ought to be thinking about how you shift that burden to the system so that, for example, if you're working in a large under-resourced city that has an over representation of minorities and over representation of people with disabilities, and you can improve things systemically there, then the potential to ameliorate disparities is much greater than if you're trying to think about a program specifically for, say, African American families, or Latino families.

I'm now starting to go off on a tangent about the social justice issue. But the issue of social justice, I think, is the societal part, that we ought to be thinking about how to focus on.

It should be integrated into the recommendations we make to these Federal agencies, and to funders. But we also ought to be thinking about where those people live and where they get care.

And I'm concerned that currently they haven't been as represented as they should be on the IACC.

Dr. Insel: Jose?

Dr. Cordero: This is a very interesting discussion, and also reflecting the fact that this is my second time around here. I was in the original IACC after the Children's Health Act, when I worked at CDC. And now I'm back as a public member.

And perhaps during that I had a chance to think back where we were in that original, when we started, in terms of the call it IACC.

And actually there was something before that, the IACC or the Children's Health Act. And at that time we were looking at even the problem of how early should children with autism be recognized.

And that was before we learned the science act early, and it was before the fact that we had some trends in improving the age at where children are recognized.

And I'm pointing out that as an example. But I think that we need to look at in the big picture. Often we had very good presentations in terms of in other meetings and a cellular level in terms of inflammation and all those things.

That's really very, very important. Be we also need to look in terms of the policies at a more microlevel, where we can actually stay the course and be sure that we're moving in the right direction.

And I'm bringing that again as an example. Because for example what guides a lot of the policies, like the Healthy People 2010 now, 2020 objectives, and I'm not even sure if they will have an objective that is children with autism should be recognized, but not later than 2 years of age, for example.

But that's the kind of question, or objective, that policy makers relate, and to what resources are added, and efforts can be focused.

So it seems to me that that's the kind of reflection that we all need, in terms of looking where we were when we started, and where we are, and where the progress has been made, and what's the next steps in that progress then that should be made.

Dr. Insel: So we'll go around the table once. Before we go around the table twice, I want to just start getting you to think about what are we actually going to do. Because we're going to end this meeting in the next 45 minutes. And as far as I know, there's no other autism coordinating committee that's thinking about these things, and going to come up with a plan.

So if there's anything that's going to be done, it's going to be done by the Group that's in this room right now, who's going to make a decision about how to move forward.

So as we get into the next set of comments, I think we have some specific ideas. Alison mentioned a roadmap. I think John talked about getting letters out. Other people have talked about other kinds of approaches. But what I am hearing, just to try to distill this down, is the sort of two different pieces that people seem to want.

One is to continue with the research effort, but mostly on the accountability side now, and asking about the assessment of what we do, what we've done, and maybe not think about creating another 78 new objectives.

We already have 78. That's plenty. Let's find out which of those need to be prioritized, as Geri said.

And let's come up with a small group that are ready to move forward with perhaps a new set of things that could be done. Other people have talked about translations. So there's a research mission, and a research responsibility we have that's about the science.

There's this other piece which, whether you want to call it services, or policy, or issues related to disparities, there are lots of different sides to that, that frankly is not going to come out of the research plan. That's not what that research plan is supposed to be, and it will never do that.

I'm always thinking about my first week in this job at NIH, I gave a talk to a group of advocates, in this case about mental illness. And I was talking to them about the spectacular research that was going on in epigenetics, and genomics, and lots of other areas.

And someone got up at the back of the room and said, you know, you don't get it. This is really great. Our house is on fire and you're telling me about the chemistry of the paint. And you need to think about how to put out the fire.

So my question for this Group is we've got a great document here that's going to talk a lot about all the things that could be done over the next decade. And some of them will take 2 decades.

But what are we going to do in the short run. As David says, it may be a very short run. Some of these things, we're looking at a once in a generation point in time, in terms of policy changes.

Does the IACC want to play in that arena? And what do we want to do? And how will we do it? Should we form a task force, a Subcommittee?

It's not going to happen through these meetings, which happen every 3 or 4 months. We're going to have to have a group that really wants to dig deep and move quickly to come up with an action agenda of things that could get done. John?

Mr. Robison: Returning to the idea of some letters to the people in Government to take action, I think, Walter, your idea of developing a tool to place people in a point on the spectrum for optimum selection of services I think is an excellent idea. I wish that we were further along with something like that. With respect though to generating these letters, and asking for services to be made deliverable, through changes in our Medicare and our Federal law overseeing insurance, one thing that I think we need to keep in mind is that we have two separate groups of people.

We have the group of people, most of whom are parents who have children with autism, and the children have a diagnosis, or they have a medical file.

And often the parents have a therapy they want to give the kid. And they can't get it paid for. And that's like Problem Number 1. And that's been the main focus that we've talked about.

But in this latest iteration of our Strategic Plan here, we have said that we believe that the largest population of autistic people is actually the unrecognized adults, because all of these kids grow up.

And there clearly are more people between 18 and death than between age 3 and 18. So recognizing that, and then thinking about what I asked about the mortality study and capturing older people, like me, I realized that my medical file does not contain one single thing for an insurance investigator to find about autism.

Because no person my age in his right mind would put that in the medical file, because you know that it's simply a basis for denial of services, or rating me worse for life insurance, or who knows what else.

So if we are going to request the Secretary make a change in legislation, we have first one set of changes that apply to parents with children with a diagnosis and a proposed treatment.

And then we have the need to choose what we're going to recommend for services for what we may call the more functional end of the spectrum.

And I say that simply because they are people who escaped diagnosis into middle age. If they had more obvious impairment, they already have a diagnosis and a treatment plan. So we need to make sure that services are available to a guy who's 40 or 50 years old who thinks he has Asperger's and can't get a job, or can't keep a relationship. And the guy needs help.

And that's a huge population of people. And we can't simply turn those people away and say well, sir, go pay $1,500, get an evaluation. Come back with your evaluation and we'll talk about what to do.

I think that we need to be recommending what we're going to do with our medical system to help those people in a concrete and effective way.

And that does not happen at all today. So I think that's a big, big concern. And I almost forgot it. And I want to thank Dena behind me for texting it to me.

But it's really true. It's a very, very different situation from the people who have diagnoses, in particular parents with kids with diagnoses.

Dr. Insel: Alan.

Dr. Guttmacher: First of all, I thank Tom very much for starting the conversation this way. It's been a great conversation.

I think the challenge for us is we've got a Strategic Plan. But we really haven't been thinking strategically enough. And it's understandable; because the challenge is here we're trying to do something positive about a condition that we don't understand the etiologies.

And I purposely make that plural of, that we don't really understand the full impact of it at any point in the life cycle, let alone across the whole life cycle, let alone the longitudinal kind of fashion.

And we don't really even know for sure, obviously, the prevalence, we don't know for sure where it ends and other "typical behavior" begins, et cetera, et cetera. So it's a daunting task in many ways.

I think the Strategic Plan has been wonderful in terms of trying to go across all of that from research to services, et cetera, et cetera.

But we've done some great ground work. But now is the time to think strategically. And I don't think we have to focus on just one just one area. There have been several ideas I find particularly attractive that come up in the conversation.

But probably to get a smaller group together that can really say the question where can we have impact. We have several assets. We have a very diverse group of folks around the table. We have clearly the ability to really flash light on things. And the question is where we flash that light.

And we have some folks, particularly the Congress and the Secretary, who are most likely to pay attention to where we put that light. So I think that's really where we've got to think.

I do think there are some certain things happening now. We need to obviously keep doing research, et cetera, et cetera. But it would be a mistake not to think about some unusual scientific opportunities that present themselves right now, or unusual opportunities, such as changes in coverage, et cetera, et cetera, where we can have a once in a generation type impact.

We need to focus on those kinds of things to really think strategically, not in some ways think quite so broadly, but come up with a few areas, maybe different areas, a few particular concrete things we think we can really achieve over the next year or so.

Dr. Insel: Geri?

Dr. Dawson: So I'm going to try to offer something, that concrete idea that perhaps just people can react to.

But one possibility would be to define a set of priority areas. Because there actually have been several. And I don't think you can just lump them all together.

I really do think one of them does have to do with more understanding prevention and causes, and thinking about what it means that traffic pollution might have an impact, or what about fever during pregnancy.

So we're starting to really understand some things about the environment that we're at a point where those things may be important to look at.

The second one that we've talked about has to do with healthcare, and disparities in services. And there's a whole set of issues there.

I do think adult outcomes and setting up adults to have successful lives is such a wasteland of information and services that it deserves its own life time perspective. But that's their own area. So people could argue about those areas. But once those are defined, I think there's sort of three things that are needed.

One is what are the immediate policy recommendations that this Group could make, to both Congress and the Secretary of Health, just in the short term?

And then the second would be what are the prioritized research studies that need to be conducted? And they could be the studies that are defined as objectives.

And it's saying which was more important. Or maybe it's combining them. But if we did this study, we would really move the ball down the court.

And then the third is – and this may be too much to do in this short time, but you do have to keep that little bit of a long term vision about the roadmap of where we're going. Because the fact is we really still don't have a lot of effective treatments for the majority of people with autism. And if we don't keep moving the science along, we're going to be sorry 5 to 10 years from now that all the new information has not had an impact.

So there does have to be some forward thinking, I think, about what are the critical investments that need to be made to continue to be making scientific progress.

Dr. Insel: So just to add, Geri, I think as we think about this. If we want to dig deep on the issues of, particularly adult outcomes, which is something that has come up many, many times, there may be other people that need to be at the table, so Labor, Justice, HUD.

And one of the things we could begin to do as an action item from this discussion is to create maybe two or three groups from this group, and then add in the expertise that we don't have already on the IACC to move really quickly on developing some recommendations, and also to get the landscape in areas that we haven't got all the expertise for here. And, Noah, I don't think you've spoken about this.

Mr. Britton: So a lot of people are talking about insurance coverage, of course really important. And insurance companies don't need to care what we come up with. So why don't we just ask them what they want in order to be convinced of something.

And, John, I really want to know what it would take for you to say this is worth covering, and this is not. What could we do that would change your mind?

Mr. O’Brien: Well, I can tell you what speaks to the Medicaid directors. And I think part of it is what we've been talking about now, which is do we have some evidence. It doesn't have to be the threshold of evidence that is optimal. But do we have some evidence about what works, for whom, and for how long? That's regardless of condition. I also think to the extent there's actually good research that could be done, let's say if you provide these services, you see these outcomes.

Now, they all don't have to be, gosh, we save lots of money on healthcare costs because we did such good work on this side. But that helps.

But I also think they're looking at other things that have to do with population health, that if they saw ultimately some good progress in individual and population health they might think that this is a good long term investment.

We don't have that data. But again, I think that we've got what we've got right now. And how to use it and package in a way that would be helpful for them to understand and digest is critically important.

Mr. Britton: Can I respond to that quickly? So what you're saying is you would need longitudinal studies? Or would it be sufficient to say we have RCTs that have been done in the last 2 years that show that this mindfulness therapy has helped for decreasing depression or something?

And what I really want to know is on a concrete level what exactly you would want. And assuming that you might represent other people in the insurance field, what they would want to hear too.

Mr. O’Brien: Well, again, I think to use what you've got now, and David has done some work on this, in terms of what's the level of evidence for some of the interventions that you have now. They are what they are.

You can't create a longitudinal study tomorrow that's going to be available in 90 days. But I do think it's going to be important to think about some of those longitudinal studies, and to look at what are some of the important outcomes that you want to include as part of those longitudinal studies.

Dr. Insel: So I'm going to cut off this conversation. It's a really important question you're asking. But the problem is there are 50 different answers. Every state does this in a different way. And John has to respond to that. And that's what makes this so difficult, in a way.

But it would be, I think, one of the issues that someone could grapple with, is to ask is there a Federal role for setting a set of standards for an evidence base, which we do not have currently. We have it for small molecules, but not for psychosocial treatments. Scott?

Mr. Robertson: So just a few just quick comments. One thing is on the agencies end, if we're going get agencies, it should cover the whole cross of the Federal Government on some of these discussions, particularly on the services area, even the ones that we don't think of as directly on autism, but already made themselves onto the Committee itself.

And we're talking about Subcommittees, et cetera, for expert opinion. And I say particularly, for instance, entities like – if we do believe in a rising tide floats all boats – then why isn't the National Council on Disability, which advises the President, the Executive Branch, Congress, on disability policy matters, why aren't they part of the discussions on what we should be having in terms of the infrastructure changes around services more broadly.

The second thing is, while, I could see how the notion that was mentioned about replicating things that are already done, and not going forward with those, I think we just have to keep ourselves cognizant though, as those gaps that exist around adults, et cetera, there is no starting point.

There is nothing to replicate because we haven't done the original, there's nothing really solid on those areas. It was mentioned on the vocational thing. There's no there there already.

So let's make sure that when we're focused on say replicating and advancing the ball on things that have already been done, that we don't leave out the focus on things that we haven't started with, the holes that we haven't started digging with the shovel yet, that are in part and parcel of the process.

The third quick comment was I agree on the strategic end of things that maybe it's on a separate plan, maybe enrollments, et cetera.

Looking at low hanging fruit, and this is kind of a term of art that we use a lot in the technology arena, is what things for the best bang for a buck can we say, well, this is something we can actually do, can be accomplished in say the next 2 years, 3 years, 4 years, 5 years.

This is something that's going to take 10 years. This is something that's going to take 15, 20, 25, et cetera. Can we prioritize things out to things that could be done more quickly, that we can already say these parts of the Federal Government can tackle some of these things right now, in a shorter time, maybe an intermediate time. And these are the things they're going to take a longer timeline on things.

And I think we have already done a good job of doing that in the Strategic Plan, my understanding of thinking about that, thinking about what things could be done quickly, what things will take longer. What issues can be addressed right now that we know that they can be more easily implemented? What things are going to take longer to fix in terms of problems.

This is again, from the technology end, we do this in software as we think of what features can we implement, et cetera, in the technology end. And then we say, well, this is something that's going to be a later revision down the road.

And I think we've tried to treat everything equally when we're tackling these problems and say, well, A, B, C, D, E, F, G, H, when some of these things are things that can be done now.

And some of these things are going to be things that are going to have to take 20, 30, 40 years because they're huger problems to tackle and require more inter-collaboration among diverse perspectives.

Dr. Insel: So just to clarify, the research plan does have short-term, long-term objectives. So we've tried to do a little bit of that.

Mr. Robertson: But this kind of sets buckets of different year kind of pieces.

Dr. Insel: No, it's not prioritized in that way.

Mr. Robertson: But it could be done on the services end, that could be possible?

Dr. Insel: Well, that's what I think Geri's suggesting, is that if we begin a services effort, that we put a lot of focus on what could be done in the next 2 to 3 months.

And then what could be done thereafter? What are the things that we actually need, as you're suggesting, for vocational studies?

Where do we need more data? So it could inform the research plan, because of the absence. Susan, you want to speak to some process?

Dr. Daniels: Okay, so my role here is to help you with structure and process to accomplish your goals.

(Applause)

Dr. Daniels: So we've heard a lot of ideas. And it's wonderful to hear this discussion. One theme that I've heard from everyone is that you want to be timely.

You don't want to have something that's lengthy, that's going to take you forever until the end of the current iteration of CARA to get done.

So I wanted to think about how you can accomplish some things quickly. And right now you have structures within the two Subcommittees you already have. We don't need to recreate new structures if you are comfortable in working within those Subcommittees.

And I heard some of the topics you're bringing up are more research oriented, some of them are more services provision oriented.

And you could form Planning Groups within those Subcommittees to tackle some of these topics, and perhaps by doing letters, or statements, or things that are much faster than the type of process you just went through on the research plan.

And I don't know if that's gelling with what your idea is of what you would like to do. But it seems like that would be achievable, for example, maybe by July that you would have several statements or letters that you might be able to write within the Subcommittees, bringing in experts to help you. But you can respond to that and see if I'm correctly assessing the type of thing you might want to do.

Dr. Insel: Remind us, what is the Services Subcommittee? Because they've been rather quiet.

Dr. Daniels: Oh, sorry, the Services Research and Policy Subcommittee, SRP. And then we have a Basic and Translational Research Subcommittee that we worked within for the Strategic Plan.

Dr. Insel: Who chairs, or who co-chairs the services side of it?

Dr. Daniels: So the services side is co-chaired by David and Denise. And you and Geri are chairing the other piece.

Dr. Insel: And so what you're suggesting is if we use that structure, David and Denise could begin, just circling back to where we started with Alison's comment, they could begin this process.

As David said, we don't want to do a roadmap, but maybe to do some sort of an action agenda that the Committee could then follow-up with. Is that the idea here?

Dr. Mandell: You're looking at me as you say that.

Dr. Insel: What we're trying to do, given the limited time we have, is to distill down the sense of the group here.

What I'm hearing is there's a lot of interest from most of the people on the Committee to do something in the services arena that is not just long-term planning and more rhetoric, but actually, given where we are at this point in time, providing information that could be helpful, whether that's in the form of letters, or guidance, or –

Dr. Mandell: So maybe this puts too fine a point on it, but in addition to the process I think it would be wonderful to have a product in mind.

So the idea that we would have 2- to 3-page sets of recommendations around very specific policy initiatives that are in process, or are occurring between now and say, I don't know, 2014, that we would generate for the whole IACC for approval.

Dr. Daniels: Yes. You would have to bring anything that comes out of the Subcommittees back to the full Committee for approval.

Dr. Mandell: Right.

Mr. Robison: Well, I've offered to write them, and I'm ready to act quickly and write these letters.

Dr. Mandell: I'm grateful for that and I was very appreciative of your doing that for the Sandy Hook one. I think that these deserve reflection by a larger group.

And I think if we're going to write something that say affects private insurers, or Medicaid, then I think having the people, who live that every day, live in those systems every day, be part of the process of writing them, so that what we generate is interpretable and actionable, would be really important.

Mr. Robison: How can we do it quickly?

Dr. Dougherty: Could I just make a

suggestion that we start with people identifying problems. So maybe John could write what he sees as the problem.

And then we go from the problems to the solutions, which are these policy statements, or recommendations. Because I think we're maybe starting at solutions when we haven't clearly identified the problem. So at least that's my –

Dr. Insel: Well, you've gotten some. I think just out of this conversation we've heard about disparities, we've heard about questions about the evidence base, which I think are important.

And then the whole question of adult outcomes are issues that have come up over and over again as something that I think the Group wants to see some action on.

Dr. Dawson: I think environmental influences has to be on the table too. Even if it's just to say where are we and where do we need to be. I think it's timely.

Dr. Insel: But is that a policy services issue?

Dr. Daniels: Yes, absolutely, I think it's a policy. Yes, that would fit in with the Research Subcommittee side

Dr. Dawson: I guess I don't really see the current structure as being necessarily the best structure of the two Subcommittees that are formed. I would be okay working in that structure. But I think we're forcing something new into an old structure.

Dr. Daniels: So we could form new structures, but then that's another FACA issue to form new structures. So if we want to form a working group, then we need to get that chartered.

So I can do that, but I don't know if it's –

Dr. Dawson: How long does that take?

Dr. Daniels: I can't tell exactly how many days it'll take.

Dr. Mandell: Can I ask a point of order related to that? So let's say we kept the current structure. But let's say there were members of the basic and translational group that we wanted to have as experts, who were part of that services discussion. How easy is that to do?

Dr. Daniels: that's easy.

Dr. Mandell: Great.

Dr. Insel: Done. Done.

(laughter)

Dr. Daniels: So if you had to do voting within the Subcommittee then you would only have the Subcommittee members voting on it. But then you'd bring it to the full Committee for a vote –

Dr. Insel: Lyn.

Dr. Daniels: – if you needed to vote at all.

Ms. Redwood: One of the areas you asked about problems that we've heard over and over again, and we heard today, that I think is a violation of human rights, is lack of adequate medical care for children with autism, and adults as well.

We've heard stories over and over again where children were mismanaged, either because they couldn't talk, they couldn't verbalize their concerns.

And I think we need some statement saying that individuals with ASD deserve the same level of medical care as those without. And they deserve the same type of medical workup. So I would ask that that be a position statement that we also consider drafting.

Dr. Insel: Idil?

Ms. Abdull: And I know in the interest of time, I think if we could start maybe with some of the things, what you said for children, autism across the spectrum.

And that would fit into what you said, Lyn, that people, who were not able to communicate what they want, we need to make sure that we help them.

And also the services part, in terms of because a part of the healthcare law is going on now, I think that we should start with that.

And we want to make sure that what John

had said is that what should we pay for whom, and for how long. I don't think we can dictate insurances, but then if you think about it, I think the Obama administration has dictated them.

So the notion that we can't tell private insurances to pay for this or that, they have already done it. And they just need to do it for autism as well.

And so maybe if we can have small, three or four action items, the behavior therapy or the Floortime, whatever therapies that we have some evidence for.

Because if you remember, Secretary Rumsfeld used to say you want to go to war with the Army you have, not the one you wish for. So we need to recommend services and therapies with the research we have, not the one we wish we could have, could have, should have, would have.

And make it three or four things that – one thing that I have learned, as I advocate – that if you overwhelm these Federal agency people, they do nothing. So if we ask small, small things, maybe two, three things, and then just keep moving on up, I think that's a good idea.

Dr. Insel: Cathy?

Dr. Rice: As an overwhelmed Federal agent –

(Laughter)

Dr. Rice: No, it's true. I think actually that goes very nicely with the point I wanted to make, is that we need to be realistic about what we can do.

We cannot set policies. We cannot tell, for instance, CDC has a certain amount of money appropriated by Congress to do very specific things.

So as much as like today we had this excellent discussion about follow-up with the Somali study, we would love to do more. But we can't just make those decisions.

So I think David's approach about being very specific and targeted about what are opportunities that are happening now that are critical, and how can we agree on, I do think we need to step back and say what is our mission and vision here for services.

Is it to help provide the services and supports and access to a meaningful improved quality of life, or whatever we want to say that is? And then think of some very specific targeted activities where we can get some will around.

And as a community, we've also mentioned this today, how often our worst enemy is each other, and that we have such diversity. But then we show that diversity to the people that we're trying to show the unity to.

And I think in this situation if we, that probably didn't make any sense, except that if we can come together on a few important things, we need to keep people safe.

We've heard a lot of examples of abuse, for instance, of people's rights being violated. Those are some basic important things that we have a lot of work to do.

So let's think of some of those really core critical things that we can get some good will around, but be realistic about the fact that we're all part of the solution too.

So we have to go back to our own communities, our organizations, our states, and figure out how to implement what we're talking about.

Dr. Insel: So mindful of the time, we've got about 10 minutes left. Let's circle back to Alison for now, you started all of this, and see where we're at in terms of how to go forward.

Ms. Singer: Well, I think the solution we've arrived at with regard to services makes sense. I just want to make sure that we don't lose sight of the points that Lyn and Geri made earlier, which is that we also have to continue to update the research plan. So we need to, in addition to creating this group that's going to work on setting these policy recommendations, we also have to create a mechanism, or a group, that's going to set priorities within the 78 heretofore unprioritized long list of things to do.

And that we'll also evaluate the progress we've made to date against those 78 priorities. So I think I'm good with where we've arrived on services. But I don't want us to forget that we also have a mandate with regard to the research plan.

Dr. Insel: So if we were to take that charge, and say that rather than creating another 30 strategic goals, objectives, or doing another update like we've just done, but to focus on the accountability part, which Lyn brought up, and the prioritizing part, which Geri brought up, would that be sufficient for the Committee in terms of what we would do in 2013?

Dr. Daniels: For the update process.

Dr. Insel: I see a lot of heads nodding, Matt?

Dr. Daniels: In terms of time lines perhaps we could do some of these policy recommendations before July. And then in July start on the evaluation process for the Strategic Plan. The Office can't run all of these things in parallel. We don't have enough –

Ms. Redwood: Can't we get more staff?

(inaudible comments.)

Ms. Redwood: Can we use that to get more staff? Because we can't be effective if we can't get some of these basic things done to have the information we need to make recommendations.

Dr. Daniels: So I was going to go through the rest of the slides, which are the Summary of Advances that the Office is working on now.

There's a Report to Congress that's due in

September that the office likely will be asked to do by the Secretary. And so we'll be doing that.

In the Portfolio Analysis, which we're also doing, plus if we're going to have possibly four little Working Groups here, there's just no way. I've got two policy analysts and myself to do the brunt of that work. And we can't be running 10 projects simultaneously.

Dr. Insel: So it's actually the same issue that we're going to come back to, just setting priorities to decide what we most want to do. Because we can't do everything. So, Matt, you had a comment.

Dr. Carey: To answer your question, I think practically I don't think there's a lot of committed money already. I think the idea of let's just keep adding goals, the kind of strategy that's gone for years doesn't really work. We can't just keep doing that.

I think we've got a document that's good, we have a plan. And let's move forward with it. And there may be some small adds, but I don't think really we can keep going and just add things.   We'll just end up with unfunded goals for the rest of the thing.

The other thing I was going throw in is maybe a little bit of a monkey wrench for part of this. We've focused a lot of discussion on insurance. And I think that's timely. And it's a nice closed space.

But when a parent says, and if I may for a moment, I think there's parallels in some of the things that John said recently as well, but I think when the parent says what's going to my kid when I die, insurance is probably not the top thing you're looking at, right.

It's more of a symptom. I think it's a lot of what David was saying. Our kids will go from being somebody that we can protect, and maybe keep the social injustice from being a big part of their life, to really going over that cliff into the social injustice world.

And I think there's a lot of things, and it becomes a lot less defined than insurance. But I think insurance is only a part. And to me I guess it is a symptom.

Dr. Insel: Yes, that's why I feel pretty strongly that if we're going into this space, I think we really have to have Labor, HUD, Justice, a bunch of others at the table to make sure that we're reaching out to those other parts of the resources that we're going to need. Jan, you've had your hand up for a long time, my apology.

Ms. Crandy: Can we have by April 9th that we have these policy change recommendations, that that's our target for the April 9th meeting? That the Committee is able to bring those back to the Committee and then we vote on those.

And then the next July meeting is for the accountability, and having the other group, since they're not going to be participating in this group, work on accountability?

Dr. Mandell: How good do you want them to be? I think certainly putting words on a page with the heading being each of these policy issues is accomplishable by April 9th, doing it in a way that they're actionable, which I think is where we hope to move, may be really challenging by April 9th.

And so what we could do is say here are the possibilities, let's prioritize within these policies, the ones that we want to particularly focus on, and try and have one or a couple done really well by then. But I like your July time line a lot better.

Dr. Insel: So can we ask you, since you seem to be pretty deep into this, given what's happening with the central benefits, Affordable Care Act implementation, parity implementation, what is the most time-critical piece of this that we ought to prioritize?

Dr. Mandell: There are a lot of people in this room who could weigh in very knowledgeably about this. Yes, I was looking at Stuart too.

So I think that the Medicaid expansion and what's happening with the insurance exchanges are the two things that I would target the most initially. I saw Peter nodding his head, to my great relief.

Dr. Insel: Would you agree with that?

Mr. Peter Bell: Yes, and we were talking about this at lunch. We understand that Federal regulations on the Affordable Care Act, at least the essential health benefits, are going to be forthcoming next month.

I know it would be a huge task to get something out of this Committee. But it would be very powerful and helpful to have a letter to the Secretary from this Group with some kind of a recommendation to support the fact that the essential health benefits in every state exchange should include behavioral health treatments as it was passed by Congress. And that was the intent. It's pretty simple and direct, and hopefully can be supported. And I guess I would just ask is there someone at this table who had a child that was diagnosed with autism, who would not want them to get access to the treatments that we all know that work.

And I think that should be universal. And to say that there isn't evidence to support that, we've been doing this for 30 years. There's a lot of evidence to support this. And 32 states have laws, 75 percent of the population, it's time to step up and support this.

Dr. Insel: So that sounds like the piece that's on fire, if I'm hearing this right. You would agree with that, so –

Dr. Mandell: I would. And the reason I put it in the Medicaid expansion second is because I think that it relates very closely to the adult question, and the idea that all of a sudden we have the potential to have a lot of adults with autism, who may or may not be carrying the diagnosis in their chart, who may or may not be insured currently, all of a sudden are going to be in the healthcare system.

Dr. Insel: So what if those were the one, two punch of this Group over the next few months? But it sounds like Number 1 needs to happen very, very quickly with a –

(inaudible comments.)

Dr. Insel: Within a week or 2.

Dr. Daniels: Yes, within a week or 2 we can't get a meeting scheduled.

Dr. Dougherty: I wonder, could I add something? I'd like to add a 1.5. I think one of the issues is we have these studies with 30 subjects and so forth. And then find out that the treatments, yes, they work. But there were some people they don't work for. They work for some people better than others.

Take advantage of this insurance expansion by collecting data on people, who get coverage for those services. So don't wait for another RCT, another replication of a study. With electronic health records, with other forms of data collection, we can collect the information as we go, as people are covered and get these services.

It will take some work, because first of all you'll need to be specific about exactly what the service is, which is a little fuzzy right now, as I understand it.

You could also do the disparities issues there, because with the insurance expansions you'll have many more people. You'll have a diverse group.

It's kind of like the philosophy of coverage with evidence development. So kind of you have to agree if you're going to get the coverage that you're going to participate in a study that will figure out, and in 5 years will have the answers, who the treatment works the best for.

Dr. Insel: But what if you're not part of the coverage?

Dr. Dougherty: Huh?

Dr. Insel: What if you're not part of the coverage? How would you get that information?

Dr. Dougherty: Well –

Dr. Insel: I guess that's what I think is the question on the table?

Dr. Dougherty: I think we could, I mean we have to figure out how many people are going to get access to the essential health benefit.

But rather than just say we need this

covered, say we need it covered and we want to use it as a way to get more information about what really –

Dr. Insel: Yes, I think, so that would be the work of your Subcommittee.

Dr. Dougherty: Yes.

Dr. Insel: Who's on that group, by the way? Can we get a show of hands of who's, so we've got several people. This is the services –

Dr. Dougherty: Research and policy.

(Simultaneous speaking)

Dr. Dawson: As needed, as a person who knows a lot about the literature.

Dr. Insel: Okay, so –

Dr. Mandell: You're all welcome as invited experts.

Dr. Insel: All right.

Dr. Mandell: Yes, the basic –

Dr. Insel: We are very close to closing time. Jan?

Ms. Crandy: Can we not, because he needs this in a month, right, this behavioral health.

Dr. Mandell: Right.

Ms. Crandy: We already know, why can't we just take a vote to support that, that this Committee supports behavioral health being part of, for autism though.

That's part of the problem in our state is they said, oh, we're going include it, but it doesn't say autism specific. So autism doesn't get included. If we didn't have an insurance mandate, we would not have it. So why can't this Committee just take a vote right now. If I make a motion –

(inaudible comments.)

Ms. Crandy: Yes, I would make a motion.

Mr. Robertson: Can I get some clarification though. Would this be inclusive of some of these other things that aren't covered always by insurance too, like OT, et cetera?

I just wonder whether, give me the notion of clarifying what we're exactly voting on in terms of what's getting added to coverage.

Because there's a lot of things that are excluded that benefit autistic people that we already have evidence for, OT, speech, et cetera, that aren't not just behavior specific things. There's a wide swath of things that insurance isn't always covering.

Dr. Insel: I think before we could vote on anything we'd have to have a pretty clear understanding of what it is we're asking for.

Because as John said before, you want to do this right. Since we do have a group that's going to bring the expertise to the table, hopefully they could meet very quickly.

We understand the clock is ticking, that we would have to respond rapidly. We've had a conversation today about whether there's other things that can be done even in the interim.

Because I think actually some of this will have to be done even this week or next week. But we may not have to involve the entire Committee.

So on your behalf, I may actually try to make some inroads on some of this problem. But I think if we're going to actually have a motion, it's going to have to be spelled out a little bit better than what we've heard so far. And it's going to require much more discussion than we can do at 2 minutes of 5:00.

Dr. Daniels: If the Committee feels that they would like some kind of a statement written up, I know David has offered to write something.

You could vote on the statement once you have seen it on paper, and you know what you're voting for. And we could do a vote via email.

Normally we try to do everything in public on the phone, so people can hear any discussion. That's the only limitation if you're going to vote by email that you can't really discuss what you're voting on, because it would have to be an up or down vote.

Dr. Insel: But we can handle this the way we did the Sandy Hook –

Dr. Daniels: Right. And so if you feel comfortable going with that type of a strategy, we could –

Dr. Insel: Is there anybody who would be opposed to that approach? Idil?

Ms. Abdull: No, no, no. Well, it's not that I'm opposed. And I'm excited about that effort, the healthcare law, but I'm hesitant to say let's make sure that children or people that have private insurance get access to behavior therapy, while we are not talking so much to John and saying what about Medicaid.

That's a double standard right there. It's creating disparity. I think saying the haves should have even more have, while the not-haves, let's think about that, kick the can down the road.

Dr. Insel: So that's a discussion that we'll have to have online when John Robison, and David, and Denise can draft the first document. We do not have time to go through the public comments.

(inaudible comments.)

Dr. Insel: Susan.

Dr. Daniels: So what I can do is work with the two Subcommittee chairs to convene phone meetings within the month, because of FACA. It'll take us a few weeks to set up those meetings.

And in the meantime this document can get started. But then at those meetings you can discuss what specific projects you're going to take on.

And for now we'll work with the idea of trying to get some things done by July. And then we'll work on the Strategic Plan at that point, unless you happen to get everything done by April, and you're ready to go on the Strategic Plan in April. Then we'll start talking about that on April 9th.

Dr. Insel: And maybe we need to revisit Lyn's idea of meeting for more than 1 day. Because there's a lot to do here. Thanks, everybody. We'll be adjourning now. But the work is not over. There's lots more to do.

Ms. Singer: And we never talked about public comments.

(Whereupon, at 5:05 p.m. the Committee adjourned)